Calendar No. 818

101ST CONGRESS
2d Session

SENATE

REPORT
101-459

NATIONAL INSTITUTES OF HEALTH REAUTHORIZATION ACT OF 1990

SEPTEMBER 12 (legislative day, SEPTEMBER 10), 1990.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2857]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2857) to amend the Public Health Service Act to reauthorize certain Institutes of the National Institutes of Health, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill, as amended, do pass.

CONTENTS

	Page
Summary of the bill	14
Background	15
Committee views	20
Committee action	31
Cost estimate	31
Regulatory impact statement	34
Section-by-section analysis	34
Changes in existing law	42

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institutes of Health Reauthorization Act of 1990".

39-010

S543-27

TITLE I—REAUTHORIZATION OF CERTAIN NATIONAL INSTITUTES

SEC. 101. NATIONAL CANCER INSTITUTE AND NATIONAL HEART, LUNG, AND BLOOD INSTITUTE.

(a) AUTHORIZATION OF APPROPRIATIONS.—Section 408(a) of the Public Health Service Act (42 U.S.C. 284c(a)) is amended—

(1) in paragraph (1)—

(A) by striking out "$1,500,000,000" and all that follows through the period in subparagraph (A), and inserting in lieu thereof "$2,093,400,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994."; and

(B) by striking out "$100,000,000" and all that follows through the period in subparagraph (B) and inserting in lieu thereof "such sums as may be necessary in fiscal year 1990, $156,600,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1994."; and

(2) in paragraph (2)—

(A) by striking out "$1,100,000,000" and all that follows through the first period in subparagraph (A), and inserting in lieu thereof "$1,498,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994."; and

(B) by striking out "$100,000,000" and all that follows through the period in subparagraph (B) and inserting in lieu thereof "such sums as may be necessary in fiscal year 1990, $151,500,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1994.".

(b) RESOURCE PROGRAM.—Section 421(b) of such Act (42 U.S.C. 285b-3(b)) is amended by inserting immediately after paragraph (4) the following new paragraph:

"(5) Shall, in consultation with the advisory council for the Institute, support appropriate programs of training and education, including continuing education and laboratory and clinical research training.".

SEC. 102. NATIONAL LIBRARY OF MEDICINE.

Section 469 of the Public Health Service Act (42 U.S.C. 286b) is amended by striking out "$14,000,000" and all that follows through the first period and inserting in lieu thereof "$40,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.".

SEC. 103. NATIONAL RESEARCH SERVICE AWARDS.

Section 487(d) of the Public Health Service Act (42 U.S.C. 288(d)) is amended by striking out "$300,000,000" and all that follows through the first period and inserting in lieu thereof "$415,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.".

SEC. 104. PAPERWORK REDUCTION.

Section 465(d)(2) of the Public Health Service Act (42 U.S.C. 286(d)(2)) is amended—

(1) by striking out "Rules" and inserting in lieu thereof "Notwithstanding any other provision of law, rules";

(2) in subparagraph (B), by striking out "or" at the end thereof;

(3) in subparagraph (C), by striking out the period and inserting in lieu thereof "; or"; and

(4) by adding at the end thereof the following new subparagraph:

"(D) under licensing arrangements that provide for quality control and full recovery of access costs.".

SEC. 105. NATIONAL COMMISSION ON SLEEP DISORDERS RESEARCH.

Section 162 of the Health Omnibus Programs Extension of 1988 (Public Law 100-607) is amended—

(1) in subsection (h), by inserting "and the Alcohol, Drug Abuse and Mental Health Administration" after "National Institutes of Health"; and

(2) in subsection (i), by striking out "18 months" and inserting in lieu thereof "24 months".

SEC. 106. TRANSFER OF PROVISIONS.

(a) IN GENERAL.—Section 12 of the Health Research Extension Act of 1985 (42 U.S.C. 285e-2 note) is—

(1) transferred to subpart 5 of part C of title IV of the Public Health Service Act (42 U.S.C. 285e et seq.);

(2) redesignated as section 445G; and

(3) inserted after section 445F (42 U.S.C. 285e-8).

(b) AVAILABILITY OF APPROPRIATIONS.—With respect to amounts made available in appropriations Acts for the purpose of carrying out the program transferred by subsection (a) to the Public Health Service Act, such subsection shall not be construed to affect the availability of such funds for such purpose.

(c) REAUTHORIZATION AND TECHNICAL AMENDMENT.—

(1) REAUTHORIZATIONS.—Subsection (c) of section 445G of the Public Health Service Act (as so redesignated) is amended to read as follows:

"(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for grants under subsection (a), $8,000,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1994.".

(2) TECHNICAL AMENDMENT.—Section 445G(a) of such Act (as so redesignated) is amended by striking out "and its incidence in the United States".

SEC. 107. NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION.

Section 478(c) of the Public Health Service Act (42 U.S.C. 286c(c)) is amended—

(1) by striking out "$8,000,000" and inserting in lieu thereof "$10,000,000";

(2) by striking out "1989" and inserting in lieu thereof "1991"; and

(3) by striking out "fiscal year 1990" and inserting in lieu thereof "each of the fiscal years 1992 through 1994".

SEC. 108. BIENNIAL REPORT ON CARCINOGENS.

Section 301(b)(4) of the Public Health Service Act (42 U.S.C. 241(b)(4)) is amended by striking out "an annual" and inserting in lieu thereof "a biennial".

SEC. 109. REAUTHORIZATION OF BIOMEDICAL ETHICS BOARD.

Section 381(e) of the Public Health Service Act (42 U.S.C. 275(e)) is amended—

(1) by striking out $2,000,000" and all that follows through "1989, and"; and

(2) by inserting after "1990" the following: ", $2,500,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1994".

SEC. 110. FETAL RESEARCH.

Section 498(c) of the Public Health Service Act (42 U.S.C. 289g(c)) is amended—

(1) by striking out paragraph (1);

(2) by redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively;

(3) in paragraph (1) (as so redesignated)—

(A) by striking out "24-month" and inserting in lieu thereof "48-month"; and

(B) by striking out "National Institute" and all that follows through "1988" and inserting in lieu thereof "National Institutes of Health Reauthorization Act of 1990"; and

(4) in paragraph (2) (as so redesignated), by striking out "1990, paragraph (2)" and inserting in lieu thereof "1994, paragraph (1)".

SEC. 111. ESTABLISHMENT OF FOUNDATION.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end thereof the following new part:

"PART H—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

"SEC. 499A. NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH.

"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—The Secretary shall establish a nonprofit corporation, to be known as the National Foundation for Biomedical Research (hereafter referred to in this section as the 'Foundation'), that shall not, except for the purposes of the Ethics in Government Act and the Technology Transfer Act, be an agency of the United States Government.

"(2) INCORPORATION.—The Secretary, in cooperation with the members of the Board of Directors under subsection (b)(4), shall incorporate the Foundation.

"(3) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of this section.

"(b) BOARD OF DIRECTORS.—

"(1) COMPOSITION.—The Board of Directors of the Foundation (hereafter referred to in this section as the 'Board') shall be composed of—

"(A) not to exceed nine voting members to be appointed by the ex officio members of the Board in accordance with this subsection;

"(B) the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, and the Surgeon General who shall be ex officio members; and

"(C) five initial members to be appointed by the ex officio members of the Board described in subparagraph (B), and the Chairperson appointed under paragraph (2), of which—

"(i) two such members shall represent the general biomedical field and one shall represent the general biobehavioral field; and

"(ii) two such members shall represent the general public.

"(2) CHAIRPERSON.—The ex officio members of the Board as described in subparagraph (B) of paragraph (1) shall appoint an individual to serve as chairperson of the Board.

"(3) TERMS AND VACANCIES.—

"(A) IN GENERAL.—The term of office of each member of the Board appointed under subparagraph (C) of paragraph (1) shall be 5 years, except that—

"(i) any individual appointed to fill a vacancy that has occurred prior to the expiration of the term for which such individual's predecessor was appointed, shall be appointed for the remainder of such predecessor's term; and

"(ii) the terms of office for the initial members of the Board shall expire as determined by the chairperson and the ex officio members of the Board at the time of the appointment.

"(B) SUBSEQUENT APPOINTMENTS.—Individuals appointed to the Board at the expiration of the term of a member shall be selected by a majority vote of all Board members at the last meeting prior to the expiration of the term of the member to be replaced.

"(C) EFFECT OF VACANCY.—A vacancy on the Board shall not affect its powers, and shall be filled in the same manner in which the original designation or appointment was made.

"(4) INCORPORATORS.—The initial members of the Board shall serve as incorporators and take whatever actions necessary to incorporate the Foundation.

"(5) COMPENSATION.—Members of the Board appointed under subparagraph (C) of paragraph (1) shall receive reasonable allowances for necessary expenses of travel, lodging, and subsistence incurred in attending meetings and other activities of the Board, as set forth in the bylaws issued by the Board.

"(c) EXECUTIVE DIRECTOR.—

"(1) IN GENERAL.—The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

"(2) COMPENSATION.—The rate of compensation of the Executive Director shall be fixed by the Board.

"(d) DUTIES.—The Foundation shall—

"(1) provide funding for the support of the endowed scientists within the organizational structure of the intramural research programs of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration;

"(2) recruit senior biomedical scientists to hold scientific positions as described in paragraph (1);

"(3) support the staffing, equipment, and space requirements for the research undertaken by the scientists described in paragraph (2);

"(4) support the stipends and research expenses of those individuals appointed under the National Institutes of Health Scholars program, who shall be appointed for 6-year terms;

"(5) negotiate a memorandum of understanding with the Director of the National Institutes of Health and the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration that specifies that Foundation scientists and personnel shall observe the ethical and procedural standards regulating research and research findings, including publications and patents, that are followed by scientists and personnel at the National Institutes of Health and the

Alcohol, Drug Abuse, and Mental Health Administration, including the Ethics in Government Act and the Technology Transfer Act; and

"(6) conduct biennial audits of the financial condition of the Foundation.

"(e) POWERS.—In order to carry out its duties under subsection (d), the Foundation is authorized to—

"(1) operate under the direction of its Board;

"(2) adopt, alter, and use a corporate seal, which shall be judicially noted;

"(3) provide for one or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;

"(4) hire, promote, compensate, and discharge officers and employees of the Foundation;

"(5) prescribe by its Board its bylaws, that shall be consistent with law, and that shall provide for the manner in which—

"(A) its officers, employees, and agents are selected;

"(B) its property is acquired, held, and transferred;

"(C) its general operations are to be conducted; and

"(D) the privileges granted by law are exercised and enjoyed;

"(6) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

"(7) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

"(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subtitle;

"(9) establish a mechanism for the selection of candidates, subject to the approval of the Director of the National Institutes of Health or the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, for the endowed scientific positions within the organizational structure of the intramural research programs of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration and candidates for participation in the National Institutes of Health Scholars program;

"(10) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

"(11) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

"(12) accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

"(13) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;

"(14) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation; and

"(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subtitle.

"(f) ADMINISTRATIVE CONTROL.—No participant in the program established under this part shall exercise any administrative control over any Federal employee.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such funds as the Secretary determines may be necessary to carry out this part, except that not more than $200,000 shall be appropriated to commence the initial operations of the Foundation, including the appointment of the Board under subsection (b). In the event that adequate amounts are not appropriated under this section, the Secretary shall make available not to exceed $200,000 from funds within the Department of Health and Human Services that are otherwise unobligated.

"(h) REPEALER.—The provisions of this part shall be repealed on the date that occurs 5 years after the date of enactment of this part, except that this subsection shall not take effect if the Foundation has not yet been incorporated under subsection (a)(2) by such date.".

SEC. 112. NATIONAL CENTER FOR HUMAN GENOME RESEARCH.

Part E of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end thereof the following new subpart:

"Subpart 4—National Center for Human Genome Research

"SEC. 486A. PURPOSE OF THE CENTER.

"The purpose of the National Center for Human Genome Research (hereinafter referred to in this subpart as the 'Center') is to—

"(1) provide advice to the Director of NIH concerning all aspects of genomic research;

"(2) coordinate the integration, review, and planning of genomic analysis research;

"(3) formulate research goals, criteria and long-range plans with the guidance of the advisory committee established under section 486C;

"(4) serve as a focal point on genomic analysis within the National Institutes of Health; and

"(5) foster, conduct, support, and administer research and research training programs directed at promoting the growth and quality of research related to mapping and sequencing of complex genomes.

"SEC. 486B. SPECIFIC AUTHORITIES.

"To carry out section 486A, the Director of the Center may—

"(1) provide research grants, or enter into research contracts and cooperative agreements, with institutions and individuals;

"(2) provide research training awards to institutions and individuals;

"(3) promote closer interaction with other bases of genomic analysis and research;

"(4) collect and disseminate research findings concerning genomic research;

"(5) develop plans for the centralized, systematic, targeted effort to create detailed maps of genomes of organisms;

"(6) sponsor scientific meetings and symposia to promote progress concerning genomic research through information sharing; and

"(7) foster national and international information exchange with industry and academia concerning research on complex genomes.

"SEC. 486C. ADVISORY COUNCIL ON COMPLEX GENOMES.

"(a) APPOINTMENT.—

"(1) IN GENERAL.—The Secretary shall appoint an advisory council for the Center which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Center on matters related to the activities carried out by and through the Center and the policies respecting such activities.

"(2) GIFTS.—The advisory council for the Center may recommend to the Secretary acceptance, in accordance with section 2101, of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Center.

"(3) DUTIES.—The advisory council for the Center—

"(A)(i) may make recommendations to the Director of the Center respecting research conducted at the Center;

"(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge; and

"(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Center;

"(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Center is concerned and with the approval of the Director of the Center make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

"(C) may appoint subcommittees and convene workshops and conferences.

"(b) MEMBERS.—The advisory council shall consist of such members as the Secretary shall appoint.

"(c) TERMS.—The term of office of an appointed member of the advisory council is 4 years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms

of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of 4 years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

"(d) CHAIRPERSON.—The chairperson of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Center to be the chairperson of the advisory council. The term of office of the chairperson shall be 2 years.

"(e) MEETINGS.—The advisory council shall meet at the call of the chairperson or upon the request of the Director of the Center, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Center.

"(f) STAFF.—The Director of the Center shall designate a member of the staff of the Center to serve as the executive secretary of the advisory council. The Director of the Center shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Center shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

"(g) COMMENTS.—The advisory council may prepare, for inclusion in the biennial report made under section 486D—

"(1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared;

"(2) comments on the progress of the Center in meeting its objectives; and

"(3) recommendations respecting the future directions and program and policy emphasis of the Center.

The advisory council may prepare such additional reports as it may determine appropriate.

"SEC. 486D. BIENNIAL REPORT.

"The Director of the Center after consultation with the advisory council for the Center, shall prepare for inclusion in the biennial report made under section 403 a biennial report that shall consist of a description of the activities of the Center and program policies of the Director of the Center in the fiscal years respecting which the report is prepared. The Director of the Center may prepare such additional reports as the Director determines appropriate. The Director of the Center shall provide the advisory council of the Center an opportunity for the submission of the written comments referred to in section 486C.".

SEC. 113. NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.

Section 446 of the Public Health Service Act (42 U.S.C. 285f) is amended by inserting before the period the following: ", including tropical diseases".

SEC. 114. CONTRACEPTION AND INFERTILITY.

(a) RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND RESEARCH CENTERS WITH RESPECT TO INFERTILITY.—Subpart 7 of part C of title IV of the Public Health Service Act (42 U.S.C. 285g et seq.) is amended by adding at the end the following new section:

"SEC. 452. RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND INFERTILITY.

"(a) IN GENERAL.—The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the purpose of improving methods of contraception and centers to conduct activities for the purpose of diagnosing and treating infertility.

"(b) NUMBER OF CENTERS.—In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with respect to contraception and for two centers with respect to infertility.

"(c) DUTIES.—

"(1) IN GENERAL.—Each center assisted under this section shall, in carrying out the purpose of the center involved—

"(A) conduct clinical and other applied research, including—

"(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and by females (including barrier methods); and

"(ii) for centers with respect to infertility, clinical trials of new or improved drugs and devices for the diagnosis and treatment of infertility in both males and females;

"(B) develop protocols for training physicians, scientists, nurses, and other health and allied health professionals

"(C) conduct training programs for such individuals;

"(D) develop model continuing education programs for such professionals; and

"(E) disseminate information to such professionals.

"(2) STIPENDS AND FEES.—A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (1), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

"(d) COORDINATION OF INFORMATION.—The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

"(e) CONSORTIUM.—Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Secretary, after consultation with the Director of the Institute.

"(f) TERM OF SUPPORT AND PEER REVIEW.—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended for one or more additional periods of not to exceed 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $20,000,000 for fiscal year 1991, $20,000,000 for fiscal year 1992, $12,000,000 for fiscal year 1993, $12,250,000 for fiscal year 1994, and $13,000,000 for fiscal year 1995.".

(b) LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY.—Part F of title IV of the Public Health Service Act (42 U.S.C. 288 et seq.) is amended by inserting after section 487A the following new section:

"SEC. 487B. LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY.

"(a) ESTABLISHMENT.—The Secretary, after consultation with the Director of the National Institute of Child Health and Human Development, shall establish a program to enter into agreements with appropriately qualified health professionals (including graduate students) under which such health professionals shall agree to conduct research with respect to contraception, or with respect to infertility, in consideration of the Secretary agreeing to repay, for each year of such service, not to exceed $20,000 of the principal and interest of the educational loans incurred by such health professionals.

"(b) ADMINISTRATIVE PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a), apply to the program established in such subsection to the same extent and in the same manner as such provisions apply to the National Health Service Loan Repayment Program.

"(c) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.

"(2) AVAILABILITY OF FUNDS.—Amounts appropriated under paragraph (1) for a fiscal year shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.".

(c) EFFECTIVE DATE.—The amendments made by this section shall become effective on October 1, 1990, or on the date of the enactment of this Act, whichever occurs later.

SEC. 115. GENERAL PROVISIONS.

Section 405(b)(1) of the Public Health Service Act (42 U.S.C. 284(b)(1)) is amended—

(1) in subparagraph (K), by striking out "and" at the end thereof;

(2) in subparagraph (L), by striking out the period and inserting in lieu thereof "; and"; and

(3) by adding immediately after subparagraph (L) the following new subparagraph:

"(M) may, notwithstanding any other provision of law, in disseminating information pursuant to this section and other laws, enter into licensing agreements that provide for quality control and the full recovery of access costs.".

TITLE II—WOMEN'S HEALTH RESEARCH

SEC. 201. INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH CONDUCTED OR SUPPORTED BY NATIONAL INSTITUTES OF HEALTH.

Part G of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 492 the following new section:

"SEC. 492A. INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH.

"(a) GENERAL REQUIREMENT.—In conducting or supporting clinical research for purposes of this title, the Secretary shall ensure that women and members of minority groups are included as subjects in each project of such research, subject to subsection (b).

"(b) NONAPPLICABILITY.—

"(1) IN GENERAL.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

"(A) is inappropriate with respect to the health of the subjects;

"(B) is inappropriate with respect to the purpose of the research; or

"(C) is inappropriate under such other circumstances as the Secretary may designate.

"(2) CRITERIA.—For purposes of paragraph (1), the Secretary shall by regulation establish criteria regarding the circumstances under which the inclusion of women and minorities in clinical research is inappropriate.

"(c) ANALYSIS OF AFFECT ON WOMEN AND MINORITY GROUPS.—In the case of any project of clinical research in which women or members of minority groups are required under subsection (a) to be included as subjects in the research, the Secretary shall ensure that the project is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being tested in the research affect women or members of minority groups, as the case may be, differently than other subjects in the research.

"(d) NOTIFICATION.—Not later than January 1, 1991, the Secretary shall notify appropriate research entities and research grant recipients of concerning the requirements of subsections (a), (b), and (c).

"(e) CLINICAL RESEARCH EQUITY SUBCOMMITTEES.—

"(1) ESTABLISHMENT.—The Secretary shall establish within the advisory council of each of the national research institutes a subcommittee to be known as the Clinical Research Equity Subcommittee (hereafter in this subsection individually referred to as a 'Subcommittee').

"(2) DUTIES.—Each Subcommittee shall review all clinical research conducted by the agency for which the advisory council involved is established. The purpose of the review shall be determining the extent to which the research is being conducted in accordance with subsections (a) through (c). Such a review shall be conducted not less than annually. Not later than 60 days after each such review, each Subcommittee shall submit to the Secretary and the Director of NIH a report describing the finding made as a result of the review.

"(3) COMPOSITION.—Each Subcommittee shall be composed of not less than 6 members of the advisory council involved. The Secretary shall designate the membership of each Subcommittee from among members of the advisory council involved who have expertise regarding clinical research on diseases, disorders, or other health conditions—

"(A) that are unique to women, more prevalent in women, or more serious for women; or

"(B) for which the risk factors or interventions are different for women.

"(4) APPOINTMENT OF ADDITIONAL MENBERS.—If the Secretary determines that an advisory council for a national research institute does not contain a sufficient number of individuals with the expertise required for purposes of paragraph (3), the Secretary shall appoint to the advisory council, from among individuals who are not officers or employees of the United States, a number of individuals necessary with respect to complying with such paragraph.

"(5) SUSPENSION OR REVOCATION OF RESEARCH AUTHORITY.—If the Secretary determines that any project of clinical research conducted by any agency of the National Institutes of Health is not being conducted in accordance with subsections (a) through (c), the Secretary shall suspend or revoke the authority for the project under such conditions as the Secretary determines appropriate.

"(f) DEFINITION.—For purposes of this section, the term 'minority groups' means racial and ethnic minority groups.".

SEC. 202. REQUIREMENT REGARDING WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH CONDUCTED OR SUPPORTED BY ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by inserting after section 507 the following new section:

"SEC. 507A. INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH.

"(a) GENERAL REQUIREMENTS.—In conducting or supporting clinical research for purposes of this title, the Secretary shall ensure that women and members of minority groups are included as subjects in each project of such research, subject to subsection (b).

"(b) NONAPPLICABILITY.—

"(1) IN GENERAL.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

"(A) is inappropriate with respect to the health of the subjects;

"(B) is inappropriate with respect to the purpose of the research; or

"(C) is inappropriate under such other circumstances as the Secretary may designate.

"(2) CRITERIA.—For purposes of paragraph (1), The Secretary shall by regulation establish criteria regarding the circumstances under which the inclusion of women and minorities in clinical research is inappropriate.

"(c) ANALYSIS OF AFFECT ON WOMEN AND MINORITY GROUPS.—In the case of any project of clinical research in which women or members of minority groups are required under subsection (a) to be included as subjects in the research, the Secretary shall ensure that the project is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being tested in the research affect women or members of minority groups, as the may be, differently than other subjects in the research.

"(d) NOTIFICATION.—Not later than January 1, 1991, the Secretary shall notify appropriate research entities and research grant recipients of the requirements concerning subsections (a), (b), and (c).

"(e) CLINICAL RESEARCH EQUITY SUBCOMMITTEES.—

"(1) ESTABLISHMENT.—The Secretary shall establish within the advisory council of each of the agencies of the Alcohol, Drug Abuse, and Mental Health Administration a subcommittee to be known as the Clinical Research Equity Subcommittee (hereafter in this subsection individually referred to as a 'Subcommittee').

"(2) DUTIES.—Each Subcommittee shall review all clinical research conducted by the agency for which the advisory council involved is established. The purpose of the review shall be determining the extent to which the research is being conducted in accordance with subsections (a) through (c). Such a review shall be conducted not less than annually. Not later than 60 days after each such review, each Subcommittee shall submit to the Secretary and the Administrator a report describing the finding made as a result of the review.

"(3) COMPOSITION.—Each Subcommittee shall be composed of not less than 6 members of the advisory council involved. The Secretary shall designate the membership of each Subcommittee from among members of the advisory council involved who have expertise regarding clinical research on diseases, disorders, or other health conditions—

"(A) that are unique to women, more prevalent in women, or more serious for women; or

"(B) for which the risk factors or interventions are different for women.

"(4) APPOINTMENT OF ADDITIONAL MEMBERS.—If the Secretary determines that an advisory council for an agency of the Alcohol, Drug Abuse, and Mental Health Administration does not contain a sufficient number of individuals with the expertise required for purposes of paragraph (3), the Secretary shall appoint to the advisory council, from among individuals who are not officers or employ-

ees of the United States, a number of individuals necessary with respect to complying with such paragraph.)

"(5) SUSPENSION OR REVOCATION OF RESEARCH AUTHORITY.—If the Secretary determines that any project of clinical research conducted by any agency of the Alcohol, Drug Abuse, and Mental Health Administration is not being conducted in accordance with subsections (a) through (c), the Secretary shall suspend or revoke the authority for the project under such conditions as the Secretary determines appropriate.

"(f) DEFINITION.—For purposes of this section, the term 'minority groups' means racial and ethnic minority groups.".

SEC. 203. PEER REVIEW REGARDING INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH.

(a) NATIONAL INSTITUTES OF HEALTH.—Section 492 of the Public Health Service Act (42 U.S.C. 289a) is amended by adding at the end the following new subsection:

"(c)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding the inclusion of women and members of minority groups as subjects in the research.

"(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 492A, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.".

(b) ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION.—Section 507 of the Public Health Service Act (42 U.S.C. 290aa-5) is amended by adding at the end the following new subsection:

"(f)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding the inclusion of women and members of minority groups as subjects in the research.

"(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 507A, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.".

SEC. 204. OFFICE OF WOMEN'S HEALTH RESEARCH AND PROGRAMS.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) by redesignating parts F and G as parts G and H, respectively; and

(2) by inserting after part E the following new part:

"PART F—WOMEN'S HEALTH RESEARCH

"SEC. 486G. OFFICE OF WOMEN'S HEALTH RESEARCH.

"(a) ESTABLISHMENT.—The Secretary, acting through the Director of the National Institutes of Health, shall establish an Office of Women's Health Research (hereinafter referred to in this part as the 'Office') and provide administrative support and support services to the Director of such Office.

"(b) DIRECTOR.—The Office of Women's Health Research shall be headed by a Director who shall be appointed by the Director of the National Institutes of Health.

"(c) PURPOSE.—It shall be the purpose of the Office to ensure that research pertaining to women's health is identified and addressed throughout the research activities conducted and supported by the National Institutes of Health. The Secretary, acting through the Director of the Office, shall—

"(1) establish an intramural research program in gynecology at the National Institute of Child Health and Human Development;

"(2) establish a clinical service in gynecology; and

"(3) develop plans for and establish, not later than January 1, 1993, a Center for Women's Health Research to support research pertaining to women's health conditions.

"SEC. 486H. FUNCTIONS OF THE DIRECTOR.

"(a) IN GENERAL.—The Director of the Office of Women's Health Research shall—

"(1)(A) identify women's health research needs, including prevention research;

"(B) identify needs for coordinated research activities, especially multidisciplinary research relating to women's health, to be conducted intra and extramurally;

"(C) encourage researchers whose research is funded or supported by the National Institutes of Health to pursue research pertaining to women's health; and

"(D) support the development and expansion of clinical trials of treatments, therapies and modes of prevention that include women of all ages, races and ethnicities.

"(2) establish a coordinating council that shall be composed of the Directors, of the Institutes, Centers, Offices, and Divisions of the National Institutes of Health and of the Alcohol, Drug Abuse, and Mental Health Administration, to assist in the duties described in paragraph (1); and

"(3) establish within such Office an advisory committee to be known as the Women's Health Clinical Research Advisory Committee (hereinafter referred to in this section as the 'Committee.').

"(b) ADVISORY COMMITTEE.—

"(1) COMPOSITION.—The Committee shall be composed of not less than 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Such members shall include physicians, practitioners, scientists, and other women's health professionals whose clinical practice, research specialization, and professional expertise includes a significant focus on women's health and gender differences that effect women's health.

"(2) DUTIES.—The Committee shall—

"(A) advise the Director of the Office concerning—

"(i) appropriate research activities to be supported by the Center with respect to—

"(I) research conditions and diseases unique to, more prevalent in, or neglected concerning areas of health relating to women of all ages, ethnicities, and racial groups;

"(II) research concerning gender differences involved in clinical drug trials, with emphasis provided to pharmacological response and side effects resulting from such;

"(III) research concerning gender differences involving disease etiology, course and treatment;

"(IV) research concerning obstectrical and gynecological health, conditions, diseases, and treatment;

"(V) research concerning health conditions relating to women that require a multidisciplinary approach;

"(VI) research concerning the prevention of health conditions that effect women; and

"(VII) the merits of establishing a Center for Women's Health as an independent center within the Office of the Director rather than as a center that is part of an existing Institute;

"(B) report to the Director of the Office on research concerning women's health that is publicly and privately supported;

"(C) provide recommendations to the Director of the Office regarding the operations of the Center;

"(D) monitor the compliance of all research projects supported or conducted by the National Institutes of Health with laws and regulations relating to the inclusion of women in clinical study populations;

"(E) provide advice to the Director of the National Institutes of Health concerning the manner in which to advance and encourage research on women's health;

"(F) provide advice to the Director of the National Institutes of Health concerning the merits of establishing the Center for Women's Health as an independent Center within the Office of the Director of the National Institutes rather than as a Center that is part of an existing Institute;

"(G) request that a study be conducted by the Institute of Medicine of the National Academy of Sciences that could assist in determining the manner in which to remove obstacles to and advance and encourage research concerning women's health; and

"(H) make recommendations to the appropriate committees of Congress and to the Director of NIH for further legislative and administrative initiatives, as appropriate for achieving the purposes described in section 486G(d).

"SEC. 486I. REPORT TO THE SECRETARY.

"(a) IN GENERAL.—Not later than January 1, 1992, and biennally thereafter, the Director of the National Institutes of Health shall prepare and submit to the Secretary, a report that shall—

"(1) describe and evaluate the progress made, during the period for which such report is prepared, in research, treatment and prevention with respect women's health conducted or supported by the National Institutes of Health;

"(2) summarize and analyze expenditures, made during the period for which such report is made, for activities with respect to women's health research conducted or supported by the National Institutes of Health;

"(3) contain such recommendations as the Director of the Office for Women's Health Research considers appropriate; and

"(4) for the initial report, recommend whether the Center for Women's Health Research should be a freestanding intramural center or whether it should be an intramural center attached to an existing institute.

"(b) SUBMISSION TO CONGRESS.—The Secretary shall provide a copy of the reports submitted under subsection (a) to the appropriate Committees of Congress.

"(c) STUDY.—With respect to the study conducted under a request made under section 486H(b)(2)(G), such study shall include an examination of the infrastructure of the Institutes, the grant approval process, the peer review process with regard to the impact of such on women's health research, the manner in which to increase the number of women in senior level research positions, and a proposed research agenda for biomedical and biobehavioral research on women's health.

"SEC. 486J. DATA BANK ON WOMEN'S HEALTH AND GENDER DIFFERENCES RESEARCH.

"(a) ESTABLISHMENT OF PROGRAM.—The Director of the National Institutes of Health, after consultation with the Director of the Office of Women's Health Research and the Board of Regent's of the National Library of Medicine, shall establish, maintain, and operate a program to provide information concerning research, treatment, and prevention activities relating to women's health and gender differences.

"(b) DATA BANK.—

"(1) ESTABLISHMENT.—The Secretary shall establish a data bank to compile information concerning the results of research with respect to women's health and gender differences that effect women's health. Such data bank shall be headed by an executive director to be appointed by the Director of the Office of Women's Health Research.

"(2) CLINICAL TRIALS AND TREATMENTS.—The data bank established under paragraph (1) shall compile information concerning clinical trials and treatments with respect to women's health and gender differences.

"(3) INFORMATION.—The executive director of the data bank shall make information compiled by the data bank available through existing informational systems that provide access to health care professionals and providers, researchers, and members of the public.

"(4) REGISTRY.—

"(A) IN GENERAL.—The executive director of the data bank shall maintain a registry of ongoing clinical trials of experimental treatments for conditions and diseases unique to, or more prevalent in, health areas concerning women and gender differences, or other health areas that have been neglected with respect to research concerning women or gender differences.

"(B) INFORMATION.—Information to be maintained in the registry under this paragraph shall include—

"(i) eligibility criteria (including sex, age, ethnicity or race) for participating in clinical trials;

"(ii) the location of the clinical trial sites; and

"(iii) any other information determined appropriate by the executive director.

"(C) REQUIREMENT TO PROVIDE INFORMATION.—Not later than 21 days after the date on which the Food and Drug Administration approves the application of the sponsor of a clinical trial for an experimental treatment, such sponsor shall provide information concerning the research to be conducted under such clinical trial to the data bank. The data bank shall include information pertaining to the results of such clinical trials of such treatments, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

"SEC. 486K. DEFINITION.

"A used in this part, the term 'women's health research' includes research concerning etiology, diagnosis, prevention, health promotion, treatment, and gender differences of conditions and diseases unique to, more prevalent in, or neglected in health areas of women in all age, ethnic, and racial groups.".

SEC. 205. EFFECTIVE DATE AND APPLICABILITY OF REQUIREMENTS.

(a) EFFECTIVE DATE.—The amendments made by section 201, 202, and 203 shall apply to research proposals considered after January 1, 1991.

(b) APPLICABILITY.—The amendments made by sections 201, 202, and 203 shall apply with respect to any project of clinical research whose initial approval by the Secretary occurs after the expiration of the 90-day period beginning on the effective date of this Act.

SUMMARY OF THE BILL

The National Institutes of Health Reauthorization Act of 1990, S. 2857, amends the Public Health Service Act (PHSA) to reauthorize certain Institutes of the National Institutes of Health (NIH) and makes additional provisions as follows:

1. National Cancer Institute.—Authorizations for NCI programs are extended for four years, totalling $2,250,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

2. National Heart, Lung, and Blood Institute.—Authorizations for NHLBI programs are extended for four years, totalling $1,650,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994. NHLBI is authorized to support training and education.

3. National Library of Medicine.—Authorization for the Medical Library Assistance Program is extended for four years at $35,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994. In addition, a new program of outreach to Eastern European scientists is initiated for $5,000,000 in FY 1991 and for such sums as are necessary for FY 1992–1994.

4. National Research Service Awards.—Authorizations for the NRSA program are extended for four years at $415,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

5. Paperwork reduction.—The National Library of Medicine and the research institutes of NIH are exempted from certain provisions of the Paperwork Reduction Act which would preclude them from receiving payment for some of their services.

6. National Commission on Sleep Disorders Research.—The Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) is included in the long-range cost planning of the Commission, and the deadline for submission of the Commission's final report is extended six months.

7. Alzheimer's disease registry.—The legislation establishing the Registry is transferred from the Health Research Extension Act of 1985 to the Public Health Service Act, and authorizations are set at $8,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

8. National Center for Biotechnology Information.—The Center is reauthorized at $10,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

9. Biennial report on carcinogens.—The annual report on carcinogens is made a biennial report.

10. Biomedical Ethics Board.—The Board is reauthorized at $2,500,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

11. Fetal research.—The provision requiring that the Biomedical Ethics Advisory Committee conduct a study concerning waivers of fetal research regulations is removed. The moratorium on granting any such waivers is extended to 1994.

12. National Foundation for Biomedical Research.—The Secretary is directed to establish a nonprofit corporation, the National Foundation for Biomedical Research, which will operate within the structure of the intramural research programs of NIH and ADAMHA. Privately funded, the Foundation will seek to attract and retain internationally known scientists by offering competitive support for salaries, equipment, and space. The Foundation will also support the NIH Scholars Program through the provision of stipends and research expenses for promising younger mid-career scientists who shall be appointed for a period not to exceed six years. There will be no cost to the Federal Government beyond initial start-up expenses. Such appropriations as the Secretary determines necessary are authorized up to a limit of $200,000. This section was previously reported out of Committee in October of 1989 as S. 1391.

13. National Center for Human Gnome Research.—The Center, already established administratively at NIH, is given statutory authority in the Public Health Service Act. Its purposes and authorities are laid out and an advisory committee is provided for.

14. National Institute of Allergy and Infectious Diseases.—Research on tropical diseases is added to the mission statement of NIAID.

15. Contraception and infertility.—The National Institute of Child Health and Human Development (NICHD) is directed to fund five centers for research and training with respect to contraception and infertility. Appropriations are authorized at $20,000,000 for FY 1991, $20,000,000 for FY 1992, $12,000,000 for FY 1993, $12,250,000 for 1994, and $13,000,000 for FY 1995. A loan repayment program is authorized to repay the educational loans of health professionals who agree to conduct research with respect to contraception or infertility.

16. Women's health research.—New emphasis is given to inclusion of women and minorities as subjects in clinical research conducted or supported by NIH and ADAMHA. Each clinical research project and research proposal is to be reviewed for compliance with the new requirements. A new Office for Women's Health Research is to be established within NIH to ensure that research pertaining to women's health is identified and addressed throughout NIH. A Women's Health Clinical Research Advisory Committee is provided for, as is a data bank on women's health and gender differences research. A Center for Women's Health Research is to be established by 1993.

Background and Need for Legislation

For over 100 years the National Institutes of Health (NIH) has demonstrated scientific excellence in the pursuit of research on dis-

eases and on the fundamental secrets of human health. In the decades since World War II, the agency has led this Nation's biomedical research effort both through work in its own laboratories and by its support of researchers in laboratories all over the country.

The decade of the 1980s brought many exciting scientific advances, some of which have opened whole new fields of investigation. Unfortunately, the 1980s also brought increasing challenges to our ability to take advantage of these new opportunities because of tightening budget constraints. Funding for NIH has increased each year, but the gains after taking account of inflation have been too small to permit support of many of the key areas of research.

The most obvious problem has been the decline in NIH's ability to fund approved research grant applications. Between 1979 and 1989, the number of new and competing research project applications eligible for funding rose from 11,510 in 1979 to 18,326 in 1989. In 1979, 5,944 of those projects, or 51.6 percent, actually received funding. In 1989, only 5,383 applicants, or 29.4 percent, received any money. The other 70 percent of the researchers, "approved but unfunded," were left to try to find support for their projects elsewhere, or to abandon the particular line of inquiry. There is a danger that some researchers, particularly young investigators, may leave the field entirely if they are too discouraged about the prospects of receiving grant support. The award rate for investigators with no established track record is only about ten percent.

Overall funding levels for NIH are not specifically authorized in the Public Health Service Act, but authorizations exist for the two largest Institutes and for several important programs. The National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI) have been responsible for supporting research efforts that have led to remarkable gains in our understanding of the two biggest killers in our society, heart disease and cancer. Many more opportunities for research advances are waiting to be exploited. This legislation provides four-year reauthorizations for NCI and NLHBI at levels that will permit award rates of approximately 35 percent for extramural research grants.

Maintaining a continuing supply of scientists is critical to the future advancement of biomedical research, but the budgetary crisis is instead discouraging today's students from pursuing careers in the sciences. There has been an alarming decline in the number of students finishing doctoral level training over the last decade. The bill reauthorizes the National Research Service Awards program of training grants at levels that will markedly increase the number of trainees that can be supported by NIH and ADAMHA.

Research advances are of little use if information about them cannot be disseminated to health professionals. The Medical Library Assistance programs of the National Library of Medicine are reauthorized to expand their outreach, so that practicing physicians, working in their own offices through personal computers, can have access to current diagnostic and treatment information now available mainly through libraries. Worldwide cooperation in sharing medical knowledge is also critical to the wise use of resources. Many countries lack sophisticated systems for interchange of information. The bill authorizes $5 million for the purchase and

installation of electronic equipment and onsite training of personnel to facilitate information transfers to research centers in Eastern European countries.

Another NLM program needing reauthorization is the National Center for Biotechnology Information. Its programs respond to the need for computer control of information in the expanding field of molecular biology. The Center builds new databases, develops ways to enhance and link existing ones, and develops new technologies for entering, storing, analyzing, and transmitting massive amounts of information in the field of biotechnology.

The legislation creates a National Foundation for Biomedical Research, building on the recommendation of a 1988 study committee of the Institute of Medicine of the National Academy of Sciences. The committee had been asked to look at options for maintaining the vigor of the NIH intramural research program. A particular problem has been NIH's increasingly difficulty in attracting and retaining senior investigators because of large salary discrepancies between government pay levels and those offered by universities and industry.

The study committee recommended that Congress charter a foundation to permit the private support of up to ten endowed chairs outside the Federal civil service system for distinguished investigators. Such a structure would get around civil service salary ceilings and would allow for provision of other resources such as equipment, travel expenses, and technical support staff. The report noted that "a few exceptional people added to the senior level would enhance the ability of NIH to attract superior researchers at all levels." The same strengths and weaknesses apply to the intramural programs of the three Institutes of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). The proposed Foundation would also support endowed chairs for senior scientists in biobehavioral fields.

Another recommendation by the IOM committee concerned the support of a small number of younger mid-career scientists through an NIH Scholars Program. Such a program would recruit bright young investigators who have taken their postdoctoral research training at institutions outside of NIH. Their presence would add fresh blood for the development of new research initiatives outside of the areas of interest and expertise of tenured NIH staff. The Foundation would support the Scholars program by providing stipends and research expenses.

The National Center for Human Genome Research was established administratively at NIH in October 1989, as an expansion of the original Office of Human Genome Research within the Office of the Director. It is responsible for coordinating and supporting research and research training in the area of human genome mapping and human DNA sequencing. In the past year the Center has developed a Five-Year Plan for the Human Genome Project and has supported a number of research grants and training awards. The Center is nearly fully staffed and is in the process of naming its advisory council. This legislation gives the Center statutory authority in the Public Health Service Act by laying out its purposes and authorities and providing for its advisory council.

Another important area of endeavor is research into the mysteries of human reproductive biology and fertility, and application of that research to the problems of contraception and infertility. Effective contraception is a continuing concern for a large portion of the world's population, and unintended pregnancy is a major problem in the United States. It is estimated that each year nearly half of all pregnancies in this country are unplanned, many of them due to contraceptive failure. Approximately half of those unplanned pregnancies are terminated by abortion. Conversely, according to the Office of Technology Assessment, approximately 2.4 million married couples who want to have a child find their hopes dashed by problems with infertility. The causes cannot always be diagnosed, and only about 60 percent can be treated successfully. Much more research in these areas is needed.

While the Federal Government supports some basic research in the field of reproductive health, including infertility and contraceptive research, funding in this area has not been a priority. The Federal Trade role needs to be expanded, however, because the private sector, notably the pharmaceutical industry, has for the past two decades been steadily withdrawing from research of this nature. Only one major American pharmaceutical company maintains an active research and development program in contraception, and only a few companies support research in infertility. Factors contributing to this situation include the skyrocketing costs of research, the long testing period to prove safety and efficacy of a new product, and the product liability crisis. As noted in the February 1990 report "Developing New Contraceptives: Obstacles and Opportunities" issued by the National Research Council and the Institute of Medicine, Since the introduction of the pill and the IUD in the early 1960s, no fundamentally new contraceptive methods have been approved for use in the United States.

This legislation addresses these gaps in research by providing funding for five centers to do research and development on methods of contraception and diagnosis and treatment of infertility. It also encourages young researchers to enter these fields by having the centers sponsor training programs and by authorizing an educational loan repayment program for investigators under-taking research in contraception or infertility. By promoting an enhanced Federal role, this legislation recognizes the desire of American men and women that medical science give them more options in their quest for responsible family planning.

Research on contraception and infertility are only two examples of areas of health research that have been neglected by the Federal Government. Of much broader concern is the whole area of women's health research, meaning research related to conditions that are uniqiue to or more prevalent or serious in women, or for which the risk factors or possible interventions are different for women. For years there has been an unfortunate tendency in much of medical research to direct the greatest efforts toward problems affecting large numbers of men, and to make many fewer special efforts in regard to conditions primarily affecting women. Obstetic and gynecological research has been relatively underfunded by NIH, both extramurally and in its own clinical programs.

In clinical research involving the testing of new drugs or other health interventions, not only the choice of topics but also the selection of participants for the research has tended to focus on middle-aged white males. Women's health concerns have fared better in some areas of research than in others. Cancer reseachers, for instance, have a fairly good record of including women as test subjects, while a number of large and lengthy studies on heart disease have excluded women. Men are more likely to develop coronary artery disease in middle age than are women, but heart disease is still the number one cause of death in women. It is not at all clear that advice on dietary cholesteral or on use of aspirin to prevent heart attacks, all of which was developed from studies on men, should be applied equally to women. Similar studies have not been done on women.

Efforts to involve more women in NIH-sponsored research were initiated in 1986 with an official policy statement directed at all grant applicants. In reviewing the effect of the new policy statement directed at all grant applicants. In reviewing the effect of the new policy as of early 1990, however, the General Accounting Office (GAO) found that little attention was being paid to it either by NIH or by grantees. GAO found that, in spite of several restatements of the guidelines encouraging grant recipients to include women in study populations and to analyze study results by gender, the policy of women had not been communicated consistently within NIH or to the research community. Furthermore, GAO found that there was no central source of data on the demographics of NIH study populations either in the NIH Director's Office of the Institutes. NIH's intramural research program has no policy on the inclusion of women, although development of one was recommended in an August 1989 report of the NIH Advisory Committee on Women's Health Issues.

Encouraging signs of improvement are on the horizon. In late August 1990, NIH published a strongly-worded notice on "NIH/ADAMHA Policy Concerning Inclusion Women in Study Populations." The notice reminded researchers of their obligation to ensure that "clinical research findings [are] of benefit to all persons at risk of the disease, regardless of gender." The notice made it clear that peer review groups will evaluate the proposed gender composition of study populations as part of their scoring of applications, and that NIH and ADAMHA will not fund applications unless they comply with the guidelines or offer a "compelling justificatioin" for not complying.

NIH's own focus on women's health research was sharpened in early September 1990 with its announcement of the creation of a new Office of Research on Women's Health within the NIH Director's Office. The Office will establish NIH-wide goals and policies for research related to women's health and will coordinate NIH activities undertaken in performing such research. The Committee is pleased that NIH has taken steps to establish an office and programs compatible with the new requirements for attention to women's health research that are contained in this legislation.

COMMITTEE VIEWS

The Committee finds that the performance of the National Institutes of Health has been laudable, especially given the resource constraints of the last two years. Continued progress has been made in both research and training. The Acting Director, Dr. William F. Raub, and the staff deserve to be commended for the work they have accomplished without an appointed Director.

The Institutes' record of success has continued even in the face of budget reductions. Support for new and competing grant applications in this fiscal year 1990 allowed funding of only 4,633 grants, the lowest number in over a decade. With this representing an award rate of 24.1%, the NIH is currently able to support only one grant out of every four that are approved for funding. Much good science is being put on hold. The new and competing grants represent the cutting edge of biomedical research. These are the studies that test new hypotheses, that offer new solutions and new approaches. Moreover, they are the studies that are individually subjected to the scrutiny of the peer review system where the level of scientific merit is measured, and where budgets are examined in great detail. Even the grants that are funded are being subjected to repeated, annual "downward negotiations" of 12-15%.

The Committee is aware that one of the most serious effects of this failure to support our trained and established biomedical scientists is that it discourages students. This is causing many of the best students to go into other fields rather than face the frustrations of uncertain support and repeated budget cuts.

The Committee is concerned that, with the loss of interest in the pursuit of advanced degrees in research fields, the strength of the institutions devoted to the training of students is beginning to erode.

It is the intention of the Committee that this direction be reversed. To that end, recommended authorizations for grant funding Institutes and programs have been adjusted to reflect the goal of raising the number of funded new and competing grants back to the level of 6,000 per year across the NIH. This will represent an award rate of just over 35%, with sufficient support to guarantee full funding of existing grants, marking an end to the practice of negotiated reductions. It is also the intention of the Committee that authorizations and appropriations should aim to support no fewer than 6,000 new and competing grants each year. This floor of 6,000 new and competing grants, however, will help to assure stability for the efforts of our nation's biomedical scientists.

NATIONAL CANCER INSTITUTE

The Committee expressed its appreciation for the work of the National Cancer Institute (NCI) in its development of new approaches to the treatment of the serious threat posed by cancer to the nation's health, second only to cardiovascular disease as a cause of death. Progress has been made in the diagnosis, treatment and prevention of the disease in many of its forms. The gains in all areas of research hold out promise for the development of new cures. However, nearly 900,000 new cases of cancer are reported annually with a death toll of nearly 500,000. These numbers, which

stretch across all age groups, make it essential that the Government support ample research to find cures and treatments. This is required not only because of the suffering caused by cancer, but because of the huge costs associated with cancer for treatment, as well as lost wages and lost human potential.

The Committee recognizes the importance of the efforts on the part of the Cancer Control program to educate the public about behavior that can reduce the risks of cancer. Eliminating smoking is certainly among the most important of these. Diet also deserves careful attention, given the relationship between obesity and some kinds of cancer. The efforts of the control program are also directed to the dissemination of information about the effects of the environment on risk reduction. The Institute is commended for its work in this area and encouraged to further expand the program.

The Committee is also aware of the efforts of the NCI to provide current information on the diagnosis and treatment of cancer to clinicians both here and abroad, as for example, through the International Cancer Research Data Bank (ICRDB). The ICRDB supplements other programs at the National Library of Medicine and provides a needed direct service. The Institute is encouraged to explore opportunities to further serve this special type of need.

The Committee is aware of the significant advances made by the Institute in the development of genetic treatments for cancer. These techniques are expected to open new doors on understanding the origins and treatment of cancer.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The Committee recommends a 34% increase over 1990 appropriations for the National Heart, Lung, and Blood Institute. The increase in funding authorizations will guarantee grant support at just over 35%, and protect grantees from budget cuts. Despite the squeezes of recent years, the NHLBI has continued research of the same high quality that has been a major contributor to a 43% reduction in mortality from coronary heart disease since 1972. The Institute should also be supported in its exploration and development of new areas of research opportunity, such as molecular biology.

The rapid development of new technologies in heart, lung and blood research requires continuing education programs to maintain pace with the advances. New authority in this area will support the Institute's development of specialized training and education programs that are aimed directly at the needs of the NHLBI and its staff. It mirrors similar programs that have been authorized for the National Cancer Institute.

NATIONAL LIBRARY OF MEDICINE

The National Library of Medicine is seen by the Committee as carrying the major share of responsibility for the collection and dissemination of medical information. The NLM has assumed this responsibility with skill and imagination. On the basis of proven successes, the Committee is supporting a broad expansion of the Library's capacity for the rapid transfer to the offices of individual physicians throughout the country the most current information on

diagnoses and treatment. This new capability will enable any physician's office in which there is a personal computer to receive the same information that is now available only through medical libraries. The Committee is authorizing $35 million in support of this extended outreach program.

The Committee authorizes an additional $5 million to fund information transfer to biomedical investigators in Eastern European countries. This authorization will help to firmly establish and build upon programs that have been in existence through the NCI and the NHLBI, as well as the NLM. Funding is intended to support the purchase and installation of electronic data tramsmission equipment and the on-site training of personnel to run the equipment at research centers in Eastern European countries to be selected by the Director of NIH in consultation with the NLM, the NCI and the NHLBI. The Committee will look forward to reports on the progress of this effort.

NATIONAL RESERCH SERVICE AWARD

The Committee is concerned with the reduction over the last decade in the number of doctoral level graduates in the sciences. While the causes for this are many, one salient factor has been the lessened support for training in the biomedical sciences. The trend of the last ten years has discouraged many of our best students from pursuing careers in research fields. The Committee believes this trend has to be reversed if the Nation is to sustain its preeminent position in biomedical research in the world.

Scientific progress in biomedical and biobehavioral research depends on a steady infusion of bright, young investigators. The National Research Service Awards are individual and institutional grants which support pre- and post-doctoral training of students as research scientists. The program includes support for ADAMHA as well as NIH.

Increases in the NRSA program are also necessary because of the current trends in the training and supply of scientists. It is evident there will be a surge in enrollments in college as the number of 18-year-olds expands after 1995. The faculty hired to educate the baby boom of the 1960's are still in place, but these will begin to retire in the 1990's. The demand for scientists to fill academic positions clearly will increase.

All of this is seen against the backdrop of the decline in the number of Ph.D. gradutes in the sciences. The number of Ph.D.'s granted to U.S. citizerns has declined over the past decade while the number of Ph.D. level scientitsts demanded for industry is expected to double over the next 20 years. If these trends are allowed to continue, the nation will face a serious shortfall of Ph.D. scientists by 1997, when the demand for scientists will begin to overwhelm our capacity to provide them.

This authorization represents a 31% increase over the 1990 appropriation, and should be regarded as further evidence of the Committee's intention that United States science not be allowed to drift toward mediocrity.

PAPERWORK REDUCTION

It is the intention of the committee that the provisions of the Paperwork Reduction Act not be permitted to inadvertently work a hardship on the NLM and other programs within the National Institutes of Health by disallowing the recovery of costs associated with the dissemination of information. Certain provisions of the Paperwork Reduction Act would hamper the NIH's ability to assure the quality of information disseminated under contract by non-governmental agencies. While supportive of the general intent of the Paperwork Reduction Act, it is the Committee's wish that the Institute be able to recover as much as possible of the costs associated with information dissemination and that the quality of the information be assured by the Institutes' expert staff.

NATIONAL COMMISSION ON SLEEP DISORDERS RESEARCH

The Committee finds that much research on sleep disorders is conducted through the Alcohol, Drug Abuse and Mental Health Administration. In view of this fact, it is appropriate that ADAMHA be represented in the long-range cost planning of the National Commission on Sleep Disorders Research. The deadline for the submission of the Commission's report is extended by six months to permit the members to complete their review of the work that needs to be done.

TRANSFER OF PROVISIONS

By this section, the Committee executes a technical legislative adjustment to locate the provision authorizing the Alzheimer's Disease Registry within title IV of the Public Health Service Act. The Committee recognizes the importance of the Registry and reauthorizes it for four years. The Committee takes the opportunity to advance the work of the Registry by authorizing its collection of data outside the United States. The Committee recognizes the importance of the Registry in standardizing diagnostic measures for this devastating disorder that effects the lives of so many people.

NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

The rapid growth of the biotechnology field has produced large amounts of data and has contributed to the development of new data sets. The Committee recognizes the importance of gathering and storing these data in ways they can be accurately maintained and rapidly retrieved. The Committee supports the work of the NCBI in deveoping systems for the management of these data, and expects the Center will perform an ever more vital function as the biotechnology field continues to expand.

BIENNIAL REPORT ON CARCINOGENS

The Committee concurs with the recommendation of the NIH that the Report on Carcinogens be made biennial rather than annual.

REAUTHORIZATION OF BIOMEDICAL ETHICS BOARD

The Committee continues to feel that the Biomedical Ethics Board can have a significant role in the development of guidelines for policy on biomedical issues. Removal of considerations regarding fetal research from the Board's responsibilities may help it to provide useful counsel in many other important ethical questions.

FETAL RESEARCH

The Committee extends the moratorium on waivers on federally funded fetal research. This bill deletes the requirement that this issue be examined by the Congressional Bioethics Board, though it is clear not all the issues surrounding fetal research have been thoroughly explored. It is recommended that the unanswered questions surrounding fetal research be pursued by the previously established but currently inactive Ethics Advisory Board of the DHHS.

NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

In an expression of its continuing concern over the problems of attracting and retaining senior biomedical investigators at the most distinguished level to the intramural research programs at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Association, the Committee voted to report legislation to establish the NIH Foundation for Biomedical Research. The Foundation will solicit private funds to support endowed chairs for biomedical investigators of international reputation. Funds will be provided for salaries at competitive levels, as well as for staff, equipment, and necessary space.

Creation of the Foundation was recommended in a report by a panel established by the Institute of Medicine. The Chairman of the Committee had requested that the panel look into the possibility that such a Foundation might enhance the recruitment efforts and the resources with which to recruit. The IOM Panel has enthusiastically supported the idea and suggested that the Foundation support about 10 endowed chairs for distinguished scientists. Since retention, and especially recruitment, of scientists with world class accomplishments and reputations, at the Nobel laureate level, has become inceasingly difficult, the Committee welcomes the IOM report. The Committee recognizes that the program could significant enhance the research environment at the National Institute of Health by providing an opportunity for a few of the most outstanding senior investigators who might otherwise be impossible to recruit to pursue their research interests there.

The authorizing legislation is written so that each senior investigator will be associated with an existing institute. The thrust of their research efforts will clearly fall within the mission of the Institute most closely related to their area of scientific interest. While the full costs of research conducted by the endowed scientists will be borne by the Foundation, there will be an agreement that all personnel supported by the Foundation will subscribe to the same principles of ethical conduct of research including rules governing publications and patents, as are followed by NIH investigators.

Concerns have been expressed that the existence of an independent Foundation working within the structure of the NIH might create an atmosphere of competition between regular NIH and NIH Foundation scientists. However, we have been reassured by scientists at the NIH that the existence of the Foundation, and the quality of the scientists it is structured to attract and support, would have a very positive affect on the research environment of the NIH. Aside from some differences with regard to hiring of staff and acquisition of equipment and materials, Foundation scientists will be expected to abide by all the rules, regulations, standards, and techical codes of behavior that otherwise govern the functioning of the NIH.

It must be understood that the Foundation is not seen as a final solution to the very serious problems of NIH in its efforts to attract and retain senior scientific personnel. The solution to these problems must be offered on a broader front than the Foundation was ever intended to address. While the Foundation can enrich the general environment for biomedical research at NIH, the problems of salary levels, the numbers of full-time positions available, and research space, must be dealt with through other avenues and other resources.

A second project to be supported by and operated by the Foundation is the NIH Scholars Program. This program will provide support for scientists in mid-career who have demonstrated superior research capabilities to pursue their research at the NIH for up to six years. The NIH Scholars Program is expected to have a positive effect on the research environment by bringing in fresh ideas and techniques to enhance the interchange between the community of NIH scientists and those in academic settings.

Through housed within the Foundation, the NIH Scholars would work under the supervision of the scientific directors of the Institutes that cover their area of research interest. Applicants would be recruited from among the most promising young scientists who would typically be at the assistant professor level in their academic settings. The advantage to the Scholar will be opportunity to work within the rich and stimulating setting of NIH; the advantage to NIH will be the presence of some of the brightest and most promising investigators in the country who have trained elsewhere and will bring fresh ideas with them. It is hoped, of course, that some of these scientists will elect to continue their careers at the NIH, thus helping to provide another source of promising investigators to add to the research community of NIH.

These programs will be started at minimal expense to the Federal government. Beyond the initial costs associated with establishing the Board of Directors, there will be no costs to the government. It is expected that the Foundatin will be capitalized at $50–60 million generated from private philantrophic funds in order to support the two programs described. The Committee has consulted with expert observers of the philantropic community which might be expected to contribute to this effort. The goal of $50–60 million for this purpose is felt to be very much in the realm of the possible.

The Committee feels that, if this project is successful, it is essential that the Foundation supported scientists must be totally independent of those who contribute to the Foundation. Careful

thought and planning must go into constructing the procedures and administration of the scientific programs and of the fund raising efforts of the Foundation so that they are truly insulated from each other. It is the Committee's preference that contributors be listed alphabetically only, with information regarding the extent of their contribution to be considered confidential and not intended for public release or publication. Further, it is essential that no specific contributor be able to provide support for a specific chair, scientist, or purpose. There must be no question about private interests influencing the direction of science because of their contribution to this Foundation. The Commmitte recognizes that other Foundations and Academies have succeeded in creating structures that meet these criteria. The Committee expects the Board of Directors to give this objective adequate concern and attention.

The Board of Directors is initially composed of six ex officio members; the Chairman and the ranking minority members of the Health and the Environment Subcommittee of the House Committee on Energy and Commerce, the Chairman and the ranking minority member of the Senate Committee on labor and Human Resources, the Director of the National Institutes of Health, and the Administrator of the Alcohol, Drug Abuse and Mental health Admisinstration. The ex officio members will appoint the first Chairman of the Foundation Board of Directors and, with the Chairman, the other five members of the Board. The Board shall represent the biomedical field, the biobehavioral field, and the general public. Additional committees may be appointed by the Board from time to time to accomplish specific tasks for the Foundation. Experts in biomedical and biobehavioral research, representing the intramural research program at the NIH and the academic community, will be clled upon to help select scientists to be considered for the chaired positions.

In order to succeed, the selection of the first Board Chairman is a vitally important function for the ex officio members. This person should be well acquainted with issues in the health field and have a sensitive appreciation of the relations between Congress, the NIH, and the broader health field. The person should have experience as a fund raiser, and should have an image of the Foundation that will help guide its early development so as to guarantee a strong future. A combination of experience consulting with government officials at the national level and service on the board of a major health facility would seem to be an ideal background.

Attention is called to the fact that this legislation provides that the scientists and personnel employed by the Foundation are to be subject to and guided by all the ethical and professional considerations and any restrictions to which all NIH scientists and employees are subject.

NATIONAL CENTER FOR HUMAN GENOME RESEARCH

The National Center for Human Genome Research was initiated on October 1, 1990, with the mission to coordinate human genome research across the NIH and between the NIH and the Department of Energy. The Committee's action confirms the establishment of

this important project and reflects the Committee's support of its mission.

Genome studies and the treatments that are based on this new knowledge hold promise of great benefit to mankind. For example, the gene that causes cystic fibrosis has been isolated within the last year. This finding offers renewed hope for the 30,000 children likely to die in childhood or early adulthood as a result of this illness. The opportunity to study the mechanisms of cystic fibrosis will allow scientisits to develop new treatments for this condition and ultimately possibly to correct or replace the affected gene.

The Committee shares the enthusiasm of the research community for the work of this new Center. The Committee also applauds the care with which the Center leadership is approaching the ethical issues associated with this area of reseach.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Tropical diseases have in recent years begun to show resurgent strength in the United States, as well as in other developed nations. Facilitated by the ever-increasing volume of international travel and commerce, malaria, dengue fever and other tropical diseases are surfacing within our borders. Epidemiologists warn that tropical viruses such as Lassa, Rift Valley, Marburg, and Ebola fevers pose serious potential hazards to American citizens.

The Committee bill amends the statutory statement of purpose for the National Institute of Allergy and Infectious Diseases (NIAID) to make specific reference to tropical disease research. The purpose of this provision is to stress congressional concern about tropical diseases and to establish in statute that tropical disease research should be among the priorities of the NIAID.

The Committee commends the Institute for its intramural research program on Chronic Fatigue Syndrome (CFS) and for its support for extramural CFS research. The Committee encourages the NIAID to further both its intramural and its extramural research in this area.

GENERAL PROVISIONS

The Committee recognizes that sections of the NIH other than the National Library of Medicine should enjoy the benefits of relief from certain restrictions on the Paperwork Reduction Act that interfere with the dissemination of scientific knowledge, hamper the implementation of quality control standards, and prohibit the recovery of costs associated with the accession of data. The value of the Paperwork Reduction Act is acknowledged in its other applications, but it inadvertently works to the disadvantage of programs at the NIH. The Committee wishes to remove these impediments that create risks for valued and useful programs throughout the whole of the NIH.

OFFICE FOR WOMEN'S HEALTH RESEARCH

The Committee is concerned about important research which pertains to women's health which has not been addressed within the current research programs of the National Institutes of Health. The Committee believes that the Institutes' approach to women's

health concerns should be closely examined and restructured. Provisions in the NIH reauthorization legislation provide for this.

The Committee is also requesting a study be conducted by the Institute of Medicine (IOM) to look systematically at the state of research supported by the NIH, and the Public Health Service, on women's health concerns and to prepare a proposed agenda for women's health research. The IOM study would include an examination of structural obstacles pertaining to women's health research, resource issues, and research priorities.

A report of a PHS Task Force on Women's Health Issues released in 1985 concluded that a systematic effort was needed to address the issue of gender bias in medical research and clinical practice. As a response to one issue which was raised by this report, new guidelines were issued by the NIH which addressed the specific area of incorporation of women as research subjects in clinical research projects. Despite the guidelines which described the policy for including women in clinical research, a recent study done by the United States Government Accounting Office concluded that there was poor implementation of the policy of including women. To what extent women are actually included is still not known; although efforts are underway to collect this data.

It is clear that gender bias cannot be allowed in any form, for its presence in protocol design raises questions about the scientific merit of the study.

The Committee is concerned that there are pressing areas of medical research from which women have been excluded and some research which pertains to women's health which has been neglected. One example of this is the lack of women subjects in much publicized cardiovascular research. Another is the lack of research on the transmission and treatment of AIDS in women.

There is also a question about whether broad areas of importance for women's health are receiving appropriate attention. The most notable example was the publication of the results of a study on "normal aging" in which there was no data on women! There appears to be little interest in menopause or its potential implications for the onset and treatment of diseases such as breast cancer and heart disease, or the significance of the relative absence of these conditions in premenopausal women.

The Committee is concerned that the dearth of women in senior level positions at the National Institutes of Health is a contributing factor. There is only one Institute Director who is a woman and there are few women in key decision-making positions. The Committee encourages each Institute to develop its own plan for improving the representation of women amongst its senior ranks and throughout its scientific structure.

There are also structural factors which present obstacles to the pursuit of research on women's health concerns. One structural problem is the absence of a gynecology research branch at the NIH. At the moment, there are only 3 gynecologists/obstetricians on permanent staff at the NIH. Without an intramural program in gynecology, there is no scientific lobby within the NIH which pushes for the pursuit of solutions to women's gynecological health problems. The absence of an intramural research program also has

impact on the vitality of the extramural research effort in gynecology, with a dampening effect on research in many areas.

To provide leadership in addressing some of these problems, the Committee is authorizing the establishment of an Office for Women's Health Research within the Office of the Director of NIH. The person who directs this Office shall be responsible to the Director of the NIH. It shall be the purpose of the Office to contribute to strategies to address the insufficient attention to women's health concerns within the NIH research programs.

The Committee intends that the Office have broad responsibility to work with all of the Institutes and Centers to sharpen the focus on women's health concerns, define research gaps and priorities, and facilities planning to close gaps and pursue priorities in each Institute. The Committee does not intend that this Office be solely responsible for addressing issues related to women's health and coordinating role for the separate Institutions. The Director of the Office is expected to be delegated the authority of the NIH Director to oversee the implementation of plans and policies such as the requirement for inclusion of women in clinical trials. The study requested of the Institute of Medicine will provide direction to the Office as it embarks on these tasks and contribute to the development of a specific plan for the fulfillment of the Office's general mission of improving and expanding research on women's health concerns.

The Office will also develop plans for the establishment of a Center for Women's Health Research to be opened in 1993, which will have the capacity to directly support research on women's health. The Office is expected to continue its role in policy development, implementation, and oversight in conjunction with the Center.

In order to ensure adequate representation of women in clinical research studies, the Committee is requiring the Secretary of the Department of Health and Human Services to notify researchers of the requirement that women and minorities be included in all research submitted for support after January 1, 1991. Exclusions shall be based upon demonstrated inappropriateness for the purposes of the research or the health of subjects, or for other reasons as determined by the Secretary.

The Committee is establishing within the Advisory Committees of each Institute and the agenices of the Alcohol, Drug Abuse and Mental Health Administration, Clinical Research Equity Subcommittees. These Committees shall review clinical research protocols to determine compliance with this legislation.

It is the Committee's intention that a National Center for Women's Health Research be established by January 1, 1993 after planning to be done by the Office. Amongst the capacities of the Center would be direct support for women's health research through independent and/or joint funding of women's health research projects.

The Committee has identified several areas of research which may merit direct financial support through this Center or involvement of the Center. The first is research on the unique health concerns of women which are not currently being addressed. Gynecology research is the principal example.

The second is research on health conditions or diseases which affect women differently than men. Such research could be conducted by the Center itself, by the Center in conjunction with an Institute, or by an Institute exclusively, in communication with the Center.

A general responsibility of the Office and the Center is to focus attention on those areas of medical research where gender differences may be relevant, and could be sought, but have not in the past been looked for. This will involve working with intramural and extramural researchers associated with all the Institutes and Centers.

The third areas of research which could be supported by the Center is that which requires an interdisciplinary approach and may be otherwise overlooked because it involves multiple Institutes or programs.

This legislation requires that the Director of the Office of Women's Health Research provide a recommendation to the NIH Director on whether the Center should be freestanding one within the NIH structure or whether it should become part of an existing Institute. In developing a recommendation on this question, the Director of the Office is to consult with an advisory committee. The study of the Institute of Medicine should provide perspective which will contribute to formulating a position on this question.

The Committee anticipates that the Institute of Medicine study will help provide guidance to the Office of Women's Health Research and its advisory committee, and the NIH Director, as plans are made for the establishment of a Center and the other programs delineated by this legislation.

Preceeding the establishment of a Center, the Secretary, acting through the Director of NIH, shall establish a clinical service in gynecology and an intramural research program in gynecology and obstetrics. The intramural research program in obstetrics/obstetrics might eventually be expanded into the Center or become part of the Center.

The legislation reported by the Committee will also establish a databank on women's health research. This will allow for better access to existing research on women's health and provide a stimulus to the definition areas which merit further work.

INFERTILITY AND CONTRACEPTION RESEARCH CENTERS

The committee adopted an amendment to establish five new applied research centers under the National Institute of Child Health and Human Development (NICHD), three for research into new methods of contraception, and two into new treatments for infertility. The amendment also establishes a loan repayment program to attract and train more young scientists specializing in these areas of research.

In its report, "Developing New Contraceptives," the National Research Council concluded that additional contraceptive methods that are safe, effective and acceptable within the various cultural, social, religious and ethical frameworks of our society would have a significant positive effect on human well-being. Prominent health professionals such as former Surgeon General C. Everett Koop also

have pointed out the need for more and improved methods of contraception.

There are pressing needs in the area of infertility as well; one out of six couples in the U.S. may be unable to conceive when they choose. The rates of abortion, unintended pregnancy and infertility in the United States are among the highest in the industrialized world and combine to exact staggering economic and social costs on our society. The Committee seeks to contribute to expanding research aimed at reducing these high rates and at assuring that all persons of reproductive age may be able to prevent the trauma of unintended pregnancy and the heartbreak of infertility.

The National Institute of Child Health and Human Development has been unable to give this type of research the priority it needs and deserves. Centers should help this research gain the priority attention it deserves. Center are also necessary for several reasons. Research and development problems within the complex field of fertility cannot be solved by an individual investigator working alone. To create a new contraceptive method or treatment for infertility, the concerted efforts of highly skilled scientists from a variety of disciplines are required. Without specialized centers, promising new leads may never be translated effectively into new methods or ever be made available to the public.

The lack of public and private funding has discouraged young scientists from choosing careers in this area, retarding further the development of new leads derived from basic research. Research centers should increase the interest of medical students and residents, and Ph.D. scientists, in training in this area.

Due to slow progress in this area of research, where nations around the world formerly depended upon the United States' leadership in this field, scientists from other countries now are beginning to move far ahead. By establishing these new research centers and the loan repayment program, the committee is taking an affirmative step to regain the United States' leadership in this field while at the same time reaffirming its commitment to those who are trying to plan their families.

Committee Action

VOTES IN COMMITEE

At its August 1, 1990 Executive Session, the Committee considered S. 2857 as a Committee amendment in the nature of a substitute. There was an amendment offered by Senator Harkin regarding contraceptive and infertility research centers, with a second degree amendment offered by Senator Cochran. The second degree amendment was rejected by a vote of 12 to 4; the Harkin amendment was approved by a vote of 10 to 6. Subsequently, the Committee amendment in the nature of a substitute was adopted unanimously by a vote of 16–0.

Congressional Budget Office—Cost Estimate

1. Bill number: S. 2857.

2. Bill title: National Institutes of Health Reauthorization Act of 1990.

3. Bill Status: As ordered reported by the Senate Committee on Labor and Human Resources on August 1, 1990.

4. Bill purpose: To amend the Public Health Service Act to reauthorize certain institutes of the National Institutes of Health, and for other purposes.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1991	1992	1993	1994	1995
Authorization levels subject to appropriations:					
National Cancer Institute	2,093	2,179	2,266	2,357	.....
Cancer control programs	157	163	170	176	.....
National Heart, Lung, and Blood Institute	1,499	1,560	1,622	1,687	.....
Heart, lung, and blood disease control programs	152	158	164	171	.....
National Library of Medicine	40	42	43	45	.....
National Research Service Awards	415	432	449	467	.....
Alzheimer's registry	8	8	9	9	.....
National Center for Biotechnology Information	10	10	11	11	.....
Biomedical Ethics Board	3	3	3	3	.....
National Foundation for Biomedical Research	5	6	6	6	6
National Center for Human Genome Research	62	64	67	69	72
Office of Women's Health Research	1	1	1	1	1
Contraception and Infertility Research Centers	20	20	12	12	13
Loan repayment program	2	4	4	.....	.....
Total estimated authorization levels subject to appropriations	4,466	4,650	4,827	5,016	93
Estimated outlays subject to appropriations:					
National Cancer Institute	1,005	1,988	2,215	2,304	1,219
Cancer control programs	75	149	166	172	91
National Heart, Lung, and Blood Institute	659	1,376	1,581	1,645	938
Heart, Lung, and Blood Disease Control Programs	67	139	160	166	95
National Library of Medicine	24	39	43	44	18
National Research Service Awards	21	291	428	445	439
Alzheimer's registry	2	7	8	9	6
National Center for Biotechnology Information	6	10	11	11	4
Biomedical Ethics Board	2	3	3	3	(1)
National Foundation for Biomedical Research	4	5	6	6	6
National Center for Human Genome Research	22	53	65	67	70
Office of Women's Health Research	1	1	1	1	1
Contraception and Infertility Research Centers	7	18	17	13	12
Loan repayment program	1	3	4	2	(1)
Total estimated outlays subject to appropriations	1,897	4,082	4,707	4,888	2,901
Direct spending—National Foundation for Biomedical Research:					
Budget authority	(1)	.....	.....	.....	.....
Outlays	(1)	.....	.....	.....	.....
Bill total:					
Authorization level/budget authority	4,466	4,650	4,827	5,016	93
Estimated outlays	1,897	4,082	4,707	4,888	2,901

[1] Less than $500,000.

Note.—Details in this table may not add to totals because of rounding.

The costs of this bill fall within budget function 550.

Basis of estimate: S. 2857 would reauthorize the National Cancer Institute (NCI): NCI Control Programs; the National Heart, Lung, and Blood Institute (NHLBI); NHLBI Control Programs; the National Library of Medicine; National Research Service Awards; the Alzheimer's Disease Registry; the National Center for Biotechnology Information; and the Biomedical Ethics Board. The bill pro-

vides specific fiscal year 1991 authorization levels, and such sums as may be necessary for fiscal years 1992 to 1994 for these programs. CBO estimated the 1992 to 1994 authorization levels by adjusting the 1991 authorization for projected inflation.

S. 2857 would authorize the Secretary of Health and Human Services (HHS) to establish a nonprofit corporation known as the National Foundation of Biomedical Research. While the foundation would not be an agency of the government, the bill would authorize such sums as may be necessary for its establishment. According to committee staff, the foundation, once established, would seek private contributions to support its activities. Because the amount of contributions that the foundation will initially receive is unknown, this estimate reflects the full costs of the foundation over the five-year period from fiscal year 1991 to 1995.

The bill states that no more than $200,000 should be appropriated or otherwise made available by the Secretary of HHS from unobligated funds within the Department of HHS, for the initial operations of the foundation. Therefore, appropriation action would not be needed to fund the initial operations of the foundation. All other funding for the foundation would be subject to appropriation action.

The foundation would support the salary, equipment and auxiliary expenses of selected senior biomedical scientists working on research programs of NIH, or the Alcohol, Drug Abuse, and Mental Health Administration. Based on information provided by NIH officials, CBO estimates that it would cost approximately $250,000 a year to support each scientist. Assuming the foundation supported 12 scientists, this would cost $3 million in fiscal year 1991, increasing to $3.5 million in fiscal year 1995 due to projected inflation.

The foundation also would support the stipends and research expenses of the NIH Scholars Program. In this competitive program, outstanding young scientists are appointed to independent research positions for six-year terms with the expectation that some of these scientists will continue their careers at NIH. Based on information provided by NIH, CBO estimates that it would cost about $100,000 each year to support each scholar. Assuming the foundation supported 20 scientists, the program would cost $2 million in fiscal year 1991, increasing to about $2.5 million in fiscal year 1995, due to projected inflation.

In addition, the bill authorizes the appointment of a permanent Executive Director to administer the daily operations of the foundation. Funds for salary and overhead for the director and additional staff would be needed. We estimate the costs for the administrator and two additional staff would be approximately $350,000 in fiscal year 1991, increasing to about $450,000 in fiscal year 1995 due to projected inflation.

In total, CBO estimates that the foundation would cost approximately $5.5 million in fiscal year 1991; $5.3 million would need to be appropriated. CBO estimates that the foundation could cost $6.5 million in fiscal year 1995 due to projected inflation. Some or all of the costs could be offset by voluntary contributions.

The bill would authorize the establishment of the National Center for Human Genome Research and an advisory committee for the center, to conduct and administer research and training

programs related to the mapping and sequencing of complex genomes. The bill does not state authorization levels for the center. Although the center was not previously authorized, $60 million was appropriated for the center for fiscal year 1990. CBO estimated the fiscal years 1991 to 1995 authorization levels for this program by adjusting the 1990 appropriation for projected inflation.

S. 2857 would establish an Office of Women's Health Research to make recommendations in order to reduce gender bias in the research activities conducted by NIH. The bill does not state authorization levels for the office. Based on information provided by NIH, CBO estimates that the office would cost approximately $1 million in each of fiscal years 1991 and 1995.

The bill would authorize the Director of the National Institute of Child Health and Human Development to provide funds to nonprofit entities to establish three centers to research improved methods of contraception and two centers to research improved methods for the diagnosis and treatment of infertility. The bill states authorization levels for these activities.

In addition, the bill would establish a loan repayment program at NIH to attract health professionals to research contraception or infertility issues. Under the loan repayment program, the Secretary of Health and Human services (HHS) would repay up to $20,000 of a health professional's educational loans in exchange for each year of service. The bill authorizes such sums as may be necessary in fiscal years 1991 to 1993 for this program. Assuming that 100 health professionals entered into loan repayment agreements each year, and served for the minimum two-year requirement, CBO estimates that this provision would cost $2 million in fiscal year 1991, increasing to $4 million in each of fiscal years 1992 and 1993.

This estimate assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Estimated cost to State and local government: None.
7. Estimate comparison: None.
8. Previous CBO estimate: None.
9. Estimate prepared by: Karen Graham (226-2820).
10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

Regulatory Impact

It is not anticipated that this legislation will have any regulatory impact.

Section-by-Section Analysis

S. 2857—National Institutes of Health Reauthorization Act of 1990

as reported by the Senate Committee on Labor and Human Resources

Section 1. Short Title

Section 1 cites the Act as the "National Institutes of Health Reauthorization Act of 1990."

TITLE I—REAUTHORIZATION OF CERTAIN NATIONAL INSTITUTES

Section 101. National Cancer Institute and National Heart, Lung, and Blood Institute

Section 101 amends section 408(a) of the Public Health Service Act (PHSA) to extend the authorization of appropriations for the National Cancer Institute and the National Heart, Lung, and Blood Institute for four years, FY 1991–1994. Authorizations for FY 1991 are set at a total of $2,250,000,000 for NCI ($156,000,000 for cancer control programs and $2,093,400,000 for all other programs) and at a total of $1,650,000,000 for NHLBI ($151,500,000 for control programs and $1,498,500,000 for all other programs). Such sums as are necessary are authorized for both Institutes for FY 1992–1994. PHSA section 421(b) is amended to direct NHLBI to support training and education programs, including continuing education and laboratory and clinical research training.

Section 102. National Library of Medicine

Section 102 amends PHSA section 469 to extend the authorization of appropriations for the Medical Library Assistance program for four years, FY 1991–1994. Authorizations are set at $40,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

Section 103. National Research Service Awards

Section 103 amends PHSA section 487(d) to extend the authorization of appropriations for National Research Service Awards for four years, FY 1991–1994. Authorizations are set at $415,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

Section 104. Paperwork reduction

Section 104 amends PHSA section 465(d)(2) to exempt the National Library of Medicine from certain provisions of the Paperwork Reduction Act by adding the provision that NLM may make its publications, materials, facilities, or services available under licensing arrangements that provide for quality control and full recovery of access costs.

Section 105. National Commission on Sleep Disorders Research

Section 105 amends section 162 of the Health Omnibus Programs Extension of 1988 (P.L. 100–607) by including the Alcohol, Drug Abuse and Mental Health Administration in the cost estimates developed for carrying out the long-range plan of the National Commission on Sleep Disorders Research and by extending for six months the deadline for submission of the Commission's final report.

Section 106. Transfer of provisions

Section 106 transfers section 12 of the Health Research Extension Act of 1985 (P.L. 99–158) concerning the Alzheimer's Disease Registry to a new PHSA section 445G under the subpart for the National Institute on Aging. Funds appropriated for the transferred program shall continue to be available. Authorizations of appropriations for the Registry are set at $8,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994. The Registry is for

the collection of epidemiological data about Alzheimer's disease; a technical amendment deletes a focus on its incidence in the United States.

Section 107. National Center for Biotechnology Information

Section 107 amends PHSA section 478(c) to extend the authorization of appropriations for the National Center for Biotechnology Information for four years, FY 1991–1994. Authorizations are set at $10,000,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

Section 108. Biennial report on carcinogens

Section 108 amends PHSA section 301(b)(4) concerning the Secretary's responsibility to publish a report on carcinogens by making the report biennial instead of annual.

Section 109. Reauthorization of Biomedical Ethics Board

Section 109 amends PHSA section 381(e) to extend the authorization of appropriations for the Biomedical Ethics Board for four years, FY 1991–1994. Authorizations are set at $2,500,000 for FY 1991 and such sums as are necessary for FY 1992–1994.

Section 110. Fetal research

Section 110 amends PHSA section 498(c) concerning fetal research by removing the requirement that the Biomedical Ethics Advisory Committee conduct a study concerning waivers of fetal research regulations. The moratorium on granting any such waivers is extended to 1994 (48 months from the date of enactment of this Act).

Section 111. Establishment of Foundation

Section 111 adds a new "Part H—National Foundation for Biomedical Research" to Title IV of the Public Health Service Act.

New PHSA section 499A, subsection (a), directs the Secretary of the Department of Health and Human Services to establish a nonprofit corporation, to be known as the National Foundation for Biomedical Research ("Foundation"), that will not be an agency of the United States Government except for purposes of the Ethics in Government Act and the Technology Transfer Act.

New subsection (b) describes the Board of Directors of the Foundation. The Board will be composed of (1) not to exceed nine voting members to be appointed by the ex officio members of the Board; (2) the Director of the National Institutes of Health (NIH), the Administrator of the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), and the Surgeon General, who will be ex officio members; and (3) five initial members to be appointed by the ex officio members, of whom two will represent the general biomedical field, one will represent the general biobehavioral field, and two will represent the general public. The ex officio members will also appoint the chairperson of the Board. The appointed members will generally serve for five years. Subsequent appointments will be made by majority vote of the Board members. The appointed members will receive compensation for expenses incurred in serving on the Board.

New subsection (c) provides for an Executive Director for the Foundation, to be appointed by the Board.

New subsection (d) sets out the duties of the Foundation. The Foundation will: (1) provide funding for the support of the endowed scientists within the organizational structure of the intramural research programs of NIH and ADAMHA: (2) recruit senior biomedical scientists to hold scientific positions; (3) support the staffing, equipment, and space requirements for the research undertaken by the scientists; (4) support the stipends and research expenses of NIH Scholars appointed for six-year terms; (5) negotiate a memorandum of understanding with NIH and ADAMHA specifying that Foundation scientists and personnel will observe the same ethical and procedural standards as NIH and ADAMHA employees; and (6) conduct biennial audits of the financial condition of the Foundation.

New subsection (e) sets out the powers of the Foundation necessary to carry out its duties. These include securing employees, developing bylaws, establishing a mechanism for the selection of candidates for the endowed scientific positions and NIH Scholars program, securing assistance with publications, obtaining patents and licenses, and other powers as necessary.

New subsection (f) provides that no participant in the Foundation's program shall exercise any administrative control over any Federal employee.

New subsection (g) authorizes the appropriation of such funds as the Secretary determines necessary to carry out Foundation activities, with a limit of $200,000 for initial operations. If adequate amounts are not appropriated, the Secretary is directed to make available up to $200,000 from other Department funds.

New subsection (h) provides for the repeal of this new part five years after enactment of this Act, unless the Foundation has not yet been incorporated at that time.

Section 112. National Center for Human Genome Research

Section 112 adds a new "Subpart 4—National Center for Human Genome Research" to Part E (Other Agencies of NIH) of Title IV of the Public Health Service Act.

New PHSA section 486A describes the purpose of the Center: (1) to provide advice to the NIH Director on all aspects of genomic research; (2) to coordinate the integration, review, and planning of genomic analysis research; (3) to formulate research goals, criteria, and long-range plans with the guidance of the advisory council; (4) to serve as a focal point on genomic analysis within NIH; and (5) to foster, conduct, support, and administer research and research training programs directed at promoting the growth and quality of research related to mapping and sequencing of complex genomes.

New PHSA section 486B lists the specific authorities of the Director of the Center: (1) make research grants, contracts, and cooperative agreements with institutions and individuals; (2) provide research training awards to institutions and individuals; (3) promote closer interaction with other bases of genomic analysis and research; (4) collect and disseminate research findings concerning genomic research; (5) develop plans for the centralized, systematic, targeted effort to create detailed maps of genomes of organisms; (6)

sponsor scientific meetings and symposia to promote progress concerning genomic research through information sharing; and (7) foster national and international information exchange with industry and academia concerning research on complex genomes.

New PHSA section 486C provides for an advisory council for the Center.

New subsection (a) provides that the advisory council is to advise, assist, consult with, and make recommendations to the Secretary and the Director of the Center on matters related to the Center's activities and policies. The advisory council may recommend acceptance of gifts for the Center. Duties of the advisory council include (1) making recommendations on research; (2) review of research and training grant applications and recommending approval of promising applications; (3) review of grants, contracts, and cooperative agreements; (4) collection of information on research in areas of concern to the Center and dissemination of such information; (5) convening of workshops and conferences.

New subsection (b) provides that the Secretary shall appoint the members of the advisory council.

New subsection (c) provides for a term of office on the advisory council of four years, and makes provisions for vacancies.

New subsection (d) provides for the selection of a chairperson for the advisory council, who could be the Director of the Center. The term of office of the chairperson is to be two years.

New subsection (e) provides for meetings of the advisory council at least three times per year, at the call of the chairperson or the Director.

New subsection (f) provides for an executive secretary for the advisory council from the staff of the Center, and provides for assistance and training for members of the council.

New subsection (g) provides that the advisory council may contribute comments for inclusion in the Center's biennial report. The comments may cover the council's activities, the progress of the Center, and recommendations of future directions for the Center. The council may prepare additional reports as appropriate.

New PHSA 486D provides that the Director of the Center, in consultation with the advisory council, shall prepare a biennial report describing the activities of the Center. It shall be included in the biennial report of the NIH Director.

Section 113. National Institute of Allergy and Infectious Diseases

Section 113 amends PHSA section 446 to add research on tropical diseases to the mission statement of the National Institute of Allergy and Infectious Diseases.

Section 114. Contraception and infertility

Section 114(a) adds a new "Section 452. Research Centers with Respect to Contraception and Infertility" to Subpart 7 (National Institute of Child Health and Human Development) of Part C of Title IV of the PHSA.

New subsections (a) and (b) authorize the NICHD Director to award grants or contracts, subject to the availability of appropriations, for the development and operation of three centers for re-

search on improving methods of contraception and two centers for research on diagnosing and treating infertility.

New subsection (c) provides that the duties of the centers include: (1) conducting clinical and other applied research, including clinical trials on new or improved drugs and devices for contraception and for the diagnosis and treatment of infertility; (2) developing protocols for training physicians, scientists, nurses, and other health and allied health professionals; (3) conducting training programs for such individuals; (4) developing model continuing education programs for such professionals; and (5) disseminating information to such professionals. The centers are authorized to use funds for training stipends and for fees to pay clincial trials subjects.

New subsection (d) requires the NICHD Director to provide for the coordination of information among the centers.

New subsection (e) provides that each center is to be located either in a single institution, or be formed from a consortium of cooperating institutions.

New subsection (f) provides that a center may be supported for up to five years, and may be renewed for additional periods of up to five years after appropriate technical and scientific peer review.

New subsection (g) authorizes appropriations for the centers at $20,000,000 for FY 1991, $20,000,000 for FY 1992, $12,000,000 for FY 1993, $12,250,000 for FY 1994, and $13,000,000 for FY 1995.

Section 114(b) adds a new "Section 487B. Loan Repayment Program for Research with Respect to Contraception and Infertility" to Part F (Awards and Training) of Title IV of the PHSA. The Secretary is directed to establish a loan repayment program under which appropriately qualifed health professionals (including graduate students) agree to conduct research with respect to contraception or infertility. In exchange for each year of such service, the Secretary will repay up to $20,000 of the principal and interest of the educational loan incurred by such health professionals. The provisions of the National Health Service Corps Loan Repayment Program (established in PHSA section 338B) shall apply to this new loan repayment program. Such sums as may be necessary to carry out the program are authorized for FY 1991 through FY 1993. Appropriations are to remain available for three fiscal years.

Section 114(c) sets the effective data of the amendments made by this section at October 1, 1990, or the date of enactment of this Act, whichever is later.

Section 115. General provisions

Section 115 amends PHSA section 405(b)(1) to exempt the NIH Institutes from certain provisions of the Paperwork Reduction Act. It provides that the Directors of the Institutes may, in disseminating information, enter into licensing agreements that provide for quality control and the full recovery of access costs.

TITLE II—WOMEN'S HEALTH RESEARCH

Section 201. Inclusion of women and minorities in clinical research conducted or supported by National Institutes of Health

Section 201 adds a new "Section 492A. Inclusion of Women and Minorities in Clinical Research" to Part G (General Provisions) of Title IV of the PHSA.

New subsection (a) states the general requirement for the Secretary to ensure that women and members of minority groups are included as subjects in each clinical research project.

New subsection (b) provides for the nonapplicability of subsection (a) when the inclusion of women and minorities would be inappropriate with respect to their health, the purpose of the research, or under other circumstances. The Secretary must by regulation establish criteria regarding such circumstances.

New subsection (c) requires the Secretary to ensure that clinical research projects are designed so that analysis may be done on whether the variables being treated in the research affect women or minorities differently than other subjects in the research.

New subsection (d) requires that the Secretary notify research entities and grant recipients of these requirements by January 1, 1991.

New subsection (e) provides for the establishment of a Clinical Research Equity Subcommittee within the advisory council of each institute. Each subcommittee is to review, at least annually, all clinical research conducted by the institute to determine compliance with the requirements of subsections (a) through (c). The subcommittee is to submit a report of each review within 60 days. Each subcommittee is to be composed of at least six members of the advisory council who have expertise in clinical research on diseases and conditions that have a unique, serious, or different effect on women. If not enough members of the advisory council have sufficient expertise, the Secretary may appoint more members. If a clinical research project conducted by NIH is out of compliance with subsections (a) through (c), the Secretary may suspend or revoke the authority for the project.

New subsection (f) defines "minority groups" to mean racial and ethnic minority groups.

Section 202. Requirement regarding women and minorities as subjects in clinical research conducted or supported by Alcohol, Drug Abuse, and Mental Health Administration

Section 202 adds a new "Section 507A. Inclusion of Women and Minorities in Clinical Research" to Part A of Title V (Alcohol, Drug Abuse, and Mental Health Programs) of the PHSA. The provisions of subsections (a) through (f) for ADAMHA are indentical to those of section 201, subsections (a) through (f), relating to NIH.

Section 203. Peer review regarding inclusion of women and minorities as subjects in clinical research

Section 203(a) amends PHSA section 492 (concerning peer review at NIH) by adding a new subsection (c) requiring that technical and scientific peer review of clinical research proposals include an evaluation of the merit of the proposal regarding the inclusion of

women and minorities as subjects, unless the proposal is not subject to the requirements concerning their inclusion.

Section 203(b) amends PHSA section 507 (concerning peer review at ADAMHA) by adding a new subsection (f) identical to the new language of section 492(c).

Section 204. Office of Women's Health Research and Programs

Section 204 amends Title IV of the Public Health Service Act by redesignating Parts F and G as Parts G and H and by inserting a new "Part F—Women's Health Research."

New PHSA section 486G provides for the establishment within NIH of an Office of Women's Health Research, to be headed by a Director appointed by the Director of NIH. The purpose of the Office is to ensure that research pertaining to women's health is identified and addressed throughout NIH. NIH is to establish an intramural research program in gynecology at the National Institute of Child Health and Human Development, establish a clinical service in gynecology, and establish, by January 1, 1993, a Center for Women's Health Research to support research pertaining to women's health conditions.

New PHSA section 486H describes the functions of the Director of the Office of Women's Health Reserach and of the advisory committee to the Office.

New subsection (a) provides that the Director shall identify women's health research needs, including prevention research and needs for coordinated research activities relating to women's health; encourage the pursuit of research on women's health; and support the development and expansion of clinical trials of treatments, therapies, and modes of prevention that include women of all ages, races, and ethnicities. The Director is to establish a coordinating council of NIH and ADAMHA institute directors and is to establish the Women's Health Clinical Research Advisory Committee.

New subsection (b) describes the composition and duties of the advisory committee. The committee shall have at least 12 public members representing various health professions relating to women's health. The committee is to advise the Director of the Office concerning research activities on the following: conditions especially affecting women; gender differences in clinical drug trials; gender differences in disease etiology, course, and treatment; obstetrical and gynecological health; research requiring a multidisciplinary approach; prevention of health conditions affecting women; and the merits of establishing a Center for Women's Health Research as an independent center within the Office of the Director rather than as a center that is part of an existing Institute. Additional duties of the committee include; report on public and private support of women's health research; advise the Director regarding operations of the Center; monitor the compliance of all NIH research projects with requirements for inclusion of women in clinical studies; advise the NIH Director on ways to advance and encourage research on women's health; advise the NIH Director on the merits of an independent Center for Women's Health Research; request an Institute of Medicine study on encouraging research on women's health; and advise the NIH Director and appropriate con-

gressional committees on further legislative and administrative initiatives to achieve the purposes of the Office.

New PHSA section 486I provides that by January 1, 1992, and biennially thereafter, the NIH Director shall submit a report to the Secretary covering: the progress made in women's health research, treatment, and prevention; expenditures for women's health research activities; recommendations of the Director of the Office for Women's Health Research; and, for the initial report, recommendations on whether the Center for Women's Health Research should be a freestanding intramural center or an intramural center attached to an existing Institute. The Secretary is directed to provide a copy of the reports to the appropriate committees of Congress. The Institute of Medicine study to be requested by the advisory committee is to include an examination of: the impact on women's health research of the infrastructure of the Institutes, the grant approval process, and the peer review process; the manner in which to increase the number of women in senior level research positions; and a proposed research agenda for biomedical and biobehavioral research on women's health.

New PHSA section 486J provides for the establishment of a data bank on women's health and gender differences research. The NIH Director is to establish, maintain, and operate a program to provide information concerning research, treatment, and prevention activities relating to women's health and gender differences. The Secretary is to establish a data bank to compile such information, including information on clinical trials and treatments with respect to women's health and gender differences. The information is to be made available through existing health care informational systems. The executive director of the data bank is to maintain a registry of ongoing clinical trials of experimental treatments relating to women's health conditions. The registry is to maintain information on eligibility criteria for participating in clinical trials, location of the clinical trial sites, and other appropriate information. Sponsors of clinical trials are to provide information to the data bank within 21 days after Food and Drug Administration approval of the trial. The data bank is to contain information on the results of such trials, including potential toxicities or adverse effects of the experimental treatment.

New PHSA section 486K defines "women's health research" to include research concerning etiology, diagnosis, prevention, health promotion, treatment, and gender differences of conditions and diseases unique to, more prevalent in, or neglected in women in all age, ethnic, and racial groups.

Section 205. Effective date and applicability of requirements

Section 205 provides that the amendments made by sections 201, 202, and 203 shall apply to research proposals considered after January 1, 1991, and to any project of clinical research approved more than 90 days after the effective date of this act.

X. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or

the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. [241] (a) * * *

* * * * * * *

(4) The Secretary shall publish [an annual] *a biennial* report which contains—

* * * * * * *

PART I—BIOMEDICAL ETHICS

SEC. 381. [275] (a) * * *

* * * * * * *

(e) To enable the Board and the Committee to carry out their functions there are authorized to be appropriated [$2,000,000 for fiscal year 1986, $2,500,000 for fiscal year 1987, $3,000,000 for fiscal year 1988, $2,000,000 for fiscal year 1989, and] $2,500,000 for fiscal year 1990, *$2,500,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1994.*

* * * * * * *

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

SEC. 405. [284] (a) * * *

* * * * * * *

(K) may accept voluntary and uncompensated services; [and]

(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute[.]; *and*

(M) may, notwithstanding any other provision of law, in disseminating information pursuant to this section and other laws, enter into licensing agreements that provide for quality control and the full recovery of access costs.

* * * * * * *

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 408. [284c] (a) * * *

* * * * * * *

(1)(A) For the National Cancer Institute (other than its programs under section 412), there are authorized to be appropriated [$1,500,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990.] *$2,093,400,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.*

(B) For the programs under section 412, there are authorized to be appropriated [$100,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990.] *such sums as may be necessary in fiscal year 1990, $156,600,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1994.*

(2)(A) For the National Heart, Lung, and Blood Institute (other than its program under section 419), there are authorized to be appropriated [$1,100,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990.] *$1,498,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.* Of the amounts appropriated for the National Heart, Lung, and Blood Institute (other than its program under section 419) for a fiscal year, the Secretary shall make available not less than 15 percent for programs respecting diseases of the lung and not less than 15 percent for programs respecting blood diseases and blood resources.

(B) For the program of the National Heart, Lung, and Blood Institute under section 419, there is authorized to be appropriated [$101,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990.] *such sums as may be necessary in fiscal year 1990, $151,500,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1994.*

* * * * * * *

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

SEC. 421. [285b-3] (a)(1) * * *

* * * * * * *

(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

(1) * * *

* * * * * * *

(5) Shall, in consultation with the advisory council for the Institute, support appropriate programs of training and education, including continuing education and laboratory and clinical research training.

* * * * * * *

DISSEMINATION PROJECT

SEC. 445F. [285e-8] (a) * * *

* * * * * * *

[SEC. 12 Sec. 445G. ALZHEIMER'S DISEASE REGISTRY.

(a) GRANT AUTHORITY.—The Director of the National Institute on Aging may make a grant to develop a registry for the collection of epidemiological data about Alzheimer's disease [and its incidence in the United States,] to train personnel in the collection of such data, and for other matters respecting such disease.

(b) QUALIFICATIONS.—To qualify for a grant under subsection (a) an applicant shall—

(1) be an accredited school of medicine or public health which has expertise in the collection of epidemiological data about individuals with Alzheimer's disease and in the development of disease registries, and

(2) have access to a large patient population, including a patient population representative of diverse ethnic backgrounds.

[(c) AUTHORIZATION.—For grants under subsection (a), there are authorized to be appropriated $2,500,000 which shall remain available until expended or through fiscal year 1989, whichever occurs first.]

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for grants under subsection (a), $8,000,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1994.

* * * * * * *

Subpart 6—National Institute of Allergy and Infectious Diseases

PURPOSE OF THE INSTITUTE

SEC. 446. [285f] The general purpose of the National Insitute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases , *including tropical diseases.*

Subpart 7—National Institute of Child Health and Human Development

* * * * * * *

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 451. [285g-3] (a) * * *

* * * * * * *

Sec. 452. RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND INFERTILITY.

(a) IN GENERAL.—The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the

purpose of improving methods of contraception and centers to conduct activities for the purpose of diagnosing and treating infertility.

(b) NUMBER OF CENTERS.—In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with respect to contraception and for two centers with respect to infertility.

(c) DUTIES.—

"(1) IN GENERAL.—Each center assisted under this section shall, in carrying out the purpose of the center involved—

(A) conduct clinical and other applied research, including—

(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and by females (including barrier methods); and

(ii) for centers with respect to infertility, clinical trials of new or improved drugs and devices for the diagnois and treatment of infertily in both males and females;

(B) develop protocols for training physcians, scientists, nurses, and other health and allied health professionals.

(C) conduct training programs for such individuals;

(D) develop model continuing education programs for such professionals; and

(E) disseminate information to such professionals.

(2) STIPENDS AND FEES.—A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (I), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

(d) COORDINATION OF INFORMATION.—The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

(e) CONSORTIUM.—Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Secretary, after consultation with the Director of the Institute.

(f) TERM OF SUPPORT AND PEER REVIEW.—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended for one or more additional periods of not to exceed 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $20,000,000 for fiscal year 1991, $20,000,000 for fiscal year 1992, $12,000,000 for fiscal year 1993, $12,250,000 for fiscal year 1994, and $13,000,000 for fiscal year 1995.

PART D—NATIONAL LIBRARY OF MEDICINE

Subpart 1—General Provisions

PURPOSE, ESTABLISHMENT, AND FUNCTIONS OF THE NATIONAL LIBRARY OF MEDICINE

SEC. 465. [286] (a) * * *

* * * * * * *

(d)(1) * * *

* * * * * * *

(2) [Rule] *Notwithstanding any other provision of law, rules.* prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

(A) without charge as a public service,

(B) upon a loan, exchange, or change basis [or]

(C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity [.]; or

(D) under licensing arrangements that provide for quality control and full recovery of access costs.

* * * * * * *

Subpart 2—Financial Assistance

AUTHORIZATION OF APPROPRIATIONS

SEC. 469. [286b] For the purpose of grants and contracts under section 472 through 476, there are authorized to be appropriated [$14,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990.] *$40,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994. Funds appropriated under this section shall remain available for such purposes until the end of the fiscal year immediately following the fiscal year for which they were appropriated.*

* * * * * * *

Subpart 3—National Center for Biotechnology Information

PURPOSE, ESTABLISHMENT FUNCTIONS, AND FUNDING OF THE NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

SEC. 478. [286c] (a) * * *

* * * * * * *

(c) For the purpose of performing the duties specified in subsection (b), there are authorized to be appropriated [$8,000,000] *$10,000,000* for fiscal year [1989] *1991* and such sums as may be necessary for [fiscal year 1990] *each of the fiscal years 1992 through 1994.* Funds appropriated under this subsection shall remain available until expended.

* * * * * * *

PART E—OTHER AGENCIES OF NIH

SUBPART 4—NATIONAL CENTER FOR HUMAN GENOME RESEARCH

SEC. 486A. PURPOSE OF THE CENTER.

The purpose of the National Center for Human Genome Research (hereinafter referred to in this subpart referred as the "Center") is to—

(1) provide advice to the director of NIH concerning all aspects of genomic research;

(2) coordinate the integration, review, and planning of genomic analysis research;

(3) formulate research goals, criteria and long-range plans with the guidance of the advisory committee established under section 486C;

(4) serve as a focal point on genomic analysis within the National Institutes of Health; and

(5) foster, conduct, support, and administer research and research training programs directed at promoting the growth and quality of research related to mapping and sequencing of complex genomes.

SEC. 486B. SPECIFIC AUTHORITIES.

To carry out section 486A, the Director of the Center may—

(1) provide research grants, or enter into research contracts and cooperative agreements, with institutions and individuals;

(2) provide research training awards to institutions and individuals;

(3) promote closer interaction with other bases of genomic analysis and research;

(4) collect and disseminate research findings concerning genomic research;

(5) develop plans for the centralized, systematic, targeted effort to create detailed maps of genomes of organisms;

(6) sponsor scientific meetings and symposia to promote progress concerning genomic research through information sharing; and

(7) foster national and international information exchange with industry and academia concerning research on complex genomes.

SEC. 486C. ADVISORY COUNCIL ON COMPLEX GENOMES.

(a) Appointment.—

(1) IN GENERAL.—The Secretary shall appoint an advisory council for the Center which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Center on matters related to the activities carried out by and through the Center and the policies respecting such activities.

(2) GIFTS.—The advisory council for the Center may recommend to the Secretary acceptance, in accordance with section 2101, of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Center.

(3) DUTIES.—The advisory council for the Center—

(A)(i) may make recommendations to the Director of the Center respecting research conducted at the Center;

(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge; and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Center;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Center is concerned and with the approval of the Director of the Center make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b) MEMBERS.—The advisory council shall consist of such members as the Secretary shall appoint.

(c) TERMS.—The term of office of an appointed member of the advisory council is 4 years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of 4 years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) CHAIRPERSON.—The chairperson of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Center to be the chairperson of the advisory council. The term of office of the chairperson shall be 2 years.

(e) MEETINGS.—The advisory council shall meet at the call of the chairperson or upon the request of the Director of the Center, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Center.

(f) STAFF.—The Director of the Center shall designate a member of the staff of the Center to serve as the executive secretary of the advisory council. The Director of the Center shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Center shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriated for their effective participation in the functions of the advisory council.

(g) COMMENTS.—The advisory council may prepare, for inclusion in the biennial report made under section 486D—

(1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared;

(2) comments on the progress of the Center in meeting its objectives; and

(3) recommendations respecting the future directions and program and policy emphasis of the Center.

The advisory council may prepare such additional reports as it may determined appropriate.

SEC. 486D. BIENNIAL REPORT.

The Director of the Center after consultation with the advisory council for the Center, shall prepare for inclusion in the biennial report made under section 403 a biennial report that shall consist of a description of the activities of the Center and program policies of the Director of the Center in the fiscal years respecting which the report is prepared. The Director of the Center may prepare such additional reports as the Director determines appropriate. The Director of the Center shall provide the advisory council of the Center an opportunity for the submission of the written comments referred to in section 486C.

PART F—WOMEN'S HEALTH RESEARCH

SEC. 486G. OFFICE OF WOMEN'S HEALTH RESEARCH.

(a) ESTABLISHMENT.—The Secretary, acting through the Director of the National Institutes of Health, shall establish an Office of Women's Health Research (hereinafter referred to in this part as the "Office") and provide administrative support and support services to the Director of such Office.

(b) DIRECTOR.—The Office of Women's Health Research shall be headed by a Director who shall be appointed by the Director of the National Institutes of Health.

(c) PURPOSE.—It shall be the purpose of the Office to ensure that research pertaining to women's health is identified and addressed throughout the research activities conducted and supported by the National Institutes of Health. The Secretary, acting through the Director of the Office, shall—

(1) establish an intramural research program in gynecology at the National Institute of Child Health and Human Development;

(2) establish a clinical service in gynecology; and

(3) develop plans for and establish, not later than January 1, 1993, a Center for Women's Health Research to support research pertaining to women's health conditions.

SEC. 486H. FUNCTIONS OF THE DIRECTOR.

(a) IN GENERAL.—The Director of the Office of Women's Health Research shall—

(1)(A) identify women's health research needs, including prevention research;

(B) identify needs for coordinated research activities, especially multidisciplinary research relating to women's health, to be conducted intra and extramurally;

(C) encourage researchers whose research is funded or supported by the National Institutes of Health to pursue research pertaining to women's health; and

(D) support the development and expansion of clinical trials of treatments, therapies and modes of prevention that include women of all ages, races and ethnicities.

(2) establish a coordinating council that shall be composed of the Directors, of the Institutes, Centers, Offices, and Divisions of the National Institutes of Health and of the Alcohol, Drug Abuse, and Mental Health Administration, to assist in the duties described in paragraph (1); and

(3) establish within such Office an advisory committee to be known as the Women's Health Clinical Research Advisory Committee (hereinafter referred to in this section as the "Committee.").

(b) ADVISORY COMMITTEE.—

(1) COMPOSITION.—The Committee shall be composed of not less than 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Such members shall include physicians, practitioners, scientists, and other women's health professionals whose clinical practice, research specialization, and professional expertise includes a significant focus on women's health and gender differences that effect women's health.

(2) DUTIES.—The Committee shall—

(A) advise the Director of the Office concerning—

(i) appropriate research activities to be supported by the Center with respect to—

(I) research conditions and diseases unique to, more prevalent in, or neglected concerning areas of health relating to women of all ages, ethnicities, and racial groups;

(II) research concerning gender differences involved in clinical drug trials, with emphasis provided to pharmacological response and side effects resulting from such;

(III) research concerning gender differences involving disease etiology, course and treatment;

(IV) research concerning obstetrical and gynecological health, conditions, diseases, and treatment;

(V) research concerning health conditions relating to women that require a multidisciplinary approach;

(VI) research concerning the prevention of health conditions that effect women; and

(VII) the merits of establishing a Center for Women's Health as an independent center within the Office of the Director rather than as a center that is part of an existing Institute;

(B) report to the Director of the Office on research concerning women's health that is publicly and privately supported;

(C) provide recommendations to the Director of the Office regarding the operations of the Center;

(D) monitor the compliance of all research projects supported or conducted by the National Institutes of Health with laws and regulations relating to the inclusion of women in clinical study populations;

(E) provide advice to the Director of the National Institutes of Health concerning the manner in which to advance and encourage research on women's health;

(F) provide advice to the Director of the National Institutes of Health concerning the merits of establishing the Center for Women's Health as an independent Center within the Office of the Director of the National Institutes rather than as a Center that is part of an existing Institute;

(G) request that a study be conducted by the Institute of Medicine of the National Academy of Sciences that could assist in determining the manner in which to remove obstacles to an advance and encourage research concerning women's health; and

(H) make recommendations to the appropriate committees of Congress and to the Director of NIH for further legislative and administrative initiatives, as appropriate for achieving the purposes described in section 486G(d).

SEC. 4861. REPORT TO THE SECRETARY.

(a) IN GENERAL.—Not later than January 1, 1992, and biennally thereafter, the Director of the National Institutes of Health shall prepare and submit to the Secretary, a report that shall—

(1) describe and evaluate the progress made, during the period for which such report is prepared, in research, treatment and prevention with respect to women's health conducted or supported by the National Institutes of Health;

(2) summarize and analyze expenditures, made during the period for which such report is made, for activities with respect to women's health research conducted or supported by the National Institutes of Health;

(3) contain such recommendations as the Director of the Office for Women's Health Research consider appropriate; and

(4) for the initial report, recommend whether the Center for Women's Health Research should be a freestanding intramural center or whether it should be an intramural center attached to an existing Institute.

(b) SUBMISSION TO CONGRESS.—The Secretary shall provide a *copy of the reports submitted under subsection (a) to the appropriate Committees of Congress.*

(c) STUDY.—With respect to the study conducted under a request made under section 486H(b)(2)(G), such study shall include an examination of the infrastructure of the Institutes, the grant approval process, the peer review process with regard to the impact of such on women's health research, the manner in which to increase the number of women in senior level research positions, and a proposed research agenda for biomedical and biobehavioral research on women's health.

SEC. 486J. DATA BANK ON WOMEN's HEALTH AND GENDER DIFFERENCES RESEARCH.

(a) ESTABLISHMENT OF PROGRAM.—The Director of the National Institutes of Health, after consultation with the Director of the Office of Women's Health Research and the Board of Regent's of the National Library of Medicine, shall establish, maintain, and operate a program to provide information concerning research, treatment, and prevention activities relating to women's health and gender differences.

(b) DATA BANK.—

(1) ESTABLISHMENT.—The Secretary shall establish a data bank to compile information concerning the results of research with respect to women's health and gender differences that effect women's health. Such data bank shall be headed by an executive director to be appointed by the Director of the Office of Women's Health Research.

(2) CLINICAL TRAILS AND TREATMENTS.—The data bank established under paragraph (1) shall compile information concerning clinical trials and treatments with respect to women's health and gender differences.

(3) INFORMATION.—The executive director of the data bank shall make information compiled by the data bank available through existing informational systems that provide access to health care professionals and providers, researchers, and members of the public.

(4) REGISTRY.—

(A) IN GENERAL.—The executive director of the data bank shall maintain a registry of ongoing clinical trials of experimental treatments for conditions and diseases unique to, or more prevalent in, health areas concerning women and gender differences, or other health areas that have been neglected with respect to research concerning women or gender differences.

(B) INFORMATION.—Information to be maintained in the registry under this paragraph shall inlcude—

(i) eligibility criteria (including sex, age, ethnicity or race) for participating in clinical trials;

(ii) the location of the clinical trial sites; and

(iii) any other information determined appropriate by the executive director.

(C) REQUIREMENT TO PROVIDE INFORMATION.—Not later than 21 days after the date on which the Food and Drug Administration approves the application of the sponsor of a clinical trial for an experimental treatment, such sponsor shall provide information concerning the research to be conducted under such clinical trial to the data bank. The data bank shall include information pertaining to the results of such clinical trials of such treatments, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

SEC. 486K. DEFINITION.

As used in this part, the term "women's health research" includes research concerning etiology, diagnosis, prevention, health promotion, treatment, and gender differences of conditions and diseases unique to, more prevalent in, or neglected in health areas of women in all age, ethnic, and racial groups.

[PART F] *PART G*—AWARDS AND TRAINING

NATIONAL RESEARCH SERVICE AWARDS

SEC. 487. [288] (a)(1) * * *

* * * * * * *

(d) For the purpose of making payments under National Research Service Awards and under grants for such Awards, there are authorized to be appropriated [$300,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990.] *$415,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1994.* Of the amounts appropriated under this subsection—

* * * * * * *

SEC. 487A. [288–1] LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) * * *

* * * * * * *

SEC. 487B. LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY.

(a) ESTABLISHMENT.—The Secretary, after consultation with the Director of the National Institute of Child Health and Human Development, shall establish a program to enter into agreements with appropriately qualified health professionals (including graduate students) under which such health professionals shall agree to conduct research with respect to contraception, or with respect to infertility, in consideration of the Secretary agreeing to repay, for each year of such service, not to exceed $20,000 of the principal and interest of the educational loans incurred by such health professionals.

(b) ADMINISTRATIVE PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a), apply to the program established in such subsection to the same extent and in the same manner as such provisions apply to the National Health Service Loan Repayment Program.

(c) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.

(2) AVAILABILITY OF FUNDS.—Amounts appropriated under paragraph (1) for a fiscal year shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

[PART G] *PART H*—GENERAL PROVISIONS

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 491. [289] (a) * * *

* * * * * * *

PEER REVIEW REQUIREMENTS

SEC. 492. [289a] (a)(1) * * *

* * * * * * *

(c)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding the inclusion of women and members of minority groups as subjects in the research.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 492A, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

SEC. 492A. INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH.

(a) GENERAL REQUIREMENT.—In conducting or supporting clinical research for purposes of this title, the Secretary shall ensure that women and members of minority groups are included as subjects in each project of such research, subject to subsection (b).

(b) NONAPPLICABILITY.—

(1) IN GENERAL.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

(A) is inappropriate with respect to the health of the subjects;

(B) is inappropriate with respect to the purpose of the research; or

(C) is in appropriate under such other circumstances as the Secretary may designate.

(2) CRITERIA.—For purposes of paragraph (1), the Secretary shall by regulation establish criteria regarding the circumstances under which the inclusion of women and minorities in clinical research is inappropriate.

(c) ANALYSIS OF AFFECT ON WOMEN AND MINORITY GROUPS.—In the case of any project of clinical research in which women or members of minority groups are required under subsection (a) to be included as subjects in the research, the Secretary shall ensure that the project is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being tested in the research affect women or members of minority groups, as the case may be, differently than other subjects in the research.

(d) NOTIFICATION.—Not later than January 1, 1991, the Secretary shall notify appropriate research entities and research grant recipients of concerning the requirements of subsections (a), (b), and (c).

(e) CLINICAL RESEARCH EQUITY SUBCOMMITTEES.—

(1) ESTABLISHMENT.—The Secretary shall establish within the advisory council of each of the national research institutes a subcommittee to be known as the Clinical Research Equity Subcommittee (hereafter in this subsection individually referred to as a "Subcommittee").

(2) DUTIES.—Each Subcommittee shall review all clinical research conducted by the agency for which the advisory council involved is established. The purpose of the review shall be determining the extent to which the research is being conducted in accordance with subsections (a) through (c). Such a review shall be conducted not less than annually. Not later than 60 days after each such review, each Subcommittee shall submit to the Secretary and the Director of NIH a report describing the finding made as a result of the review.

(3) COMPOSITION.—Each Subcommittee shall be composed of not less than 6 members of the advisory council involved. The Secretary shall designate the membership of each Subcommittee from among members of the advisory council involved who have expertise regarding clinical research on diseases, disorders, or other health conditions—

(A) that are unique to women, more prevalent in women, or more serious for women; or

(B) for which the risk factors or interventions are different for women.

(4) APPOINTMENT OF ADDITIONAL MEMBERS.—If the Secretary determines that an advisory council for a national research institute does not contain a sufficient number of individuals with the expertise required for purposes of paragraph (3), the Secretary shall appoint to the advisory council, from among individuals who are not officers or employees of the United States, a number of individuals necessary with respect to complying with such paragraph.

(5) SUSPENSION OR REVOCATION OF RESEARCH AUTHORITY.—If the Secretary determines that any project of clinical research conducted by any agency of the National Institutes of Health is not being conducted in accordance with subsections (a) through (c), the Secretary shall suspend or revoke the authority for the project under such conditions as the Secretary determines appropriate.

(f) DEFINITION.—For purposes of this section, the term "minority groups" means racial and ethnic minority groups.

* * * * * * *

FETAL RESEARCH

SEC. 498. [289g] (a) * * *

* * * * * * *

[(c)(1) The Biomedical Ethics Advisory Committee appointed under section 381 shall conduct a study of the nature, advisability,

and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of such part 46 (or any successor to such regulations). The Committee shall complete the study and report its findings to the Biomedical Ethics Board established under section 381 not later than the expiration of 24 months after the date of the enactment of the National Institute on Deafness and Other Communication Disorders and Health Research Extension Act of 1988 [enacted on November 4, 1988]. The report shall include the recommendations, if any, of the Committee on the advisability of the authority for such a waiver and the circumstances under which such a waiver might be granted. The Biomedical Ethics Board shall transmit the report to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate.]

[(2)] *(c)(1)* During the [24-month] *48-month* period beginning on the date of the enactment of the [National Institute on Deafness and Other Communication Disorders and Health Research Extension Act of 1988] *National Institutes of Health Reauthorization Act of 1990*, the Secretary may not grant (under section 46.211 of part 45 of title 46 of the Code of Federal Regulations or any successor to such section) a modification or waiver for fetal research.

[(3)] *(2)* Effective October 31, [1990, paragraph (2)] *1994, paragraph (1)* is repealed.

CONSTRUCTION OF TITLE

SEC. 499. [289h] * * *

* * * * * * *

PART H—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

SEC. 499A. NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a nonprofit corporation, to be known as the National Foundation for Biomedical Research (hereafter referred to in this section as the "Foundation"), that shall not, except for the purposes of the Ethics in Government Act and the Technology Transfer Act, be an agency of the United States Government.

(2) INCORPORATION.—The Secretary, in cooperation with the members of the Board of Directors under subsection (b)(4), shall incorporate the Foundation.

(3) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of this section.

(b) BOARD OF DIRECTORS.—

(1) COMPOSITION.—The Board of Directors of the Foundation (hereafter referred to in this section as the "Board") shall be composed of—

(A) not to exceed nine voting members to be appointed by the ex officio members of the Board in accordance with this subsection;

(B) the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, and the Surgeon General who shall be ex officio members; and

(C) five initial members to be appointed by the ex officio members of the Board described in subparagraph (B), and the Chairperson appointed under paragraph (2), of which—

(i) two such members shall represent the general biomedical field and one shall represent the general biobehavioral field; and

(ii) two such members shall represent the general public.

(2) CHAIRPERSON.—The ex offi[illegible]embers of the Board as described in subparagraph (B) of [illegible]agraph (1) shall appoint an individual to serve as chairperson of the Board.

(3) TERMS AND VACANCIES.—

(A) IN GENERAL.—The term of office of each member of the Board appointed under subparagraph (C) of paragraph (1) shall be 5 years, except that—

(i) any individual appointed to fill a vacancy that has occurred prior to the expiration of the term for which such individual's predecessor was appointed, shall be appointed for the remainder of such predecessor's term; and

(ii) the terms of office for the initial members of the Board shall expire as determined by the chairperson and the ex officio members of the Board at the time of the appointment.

(B) SUBSEQUENT APPOINTMENT.—Individuals appointed to the Board at the expiration of the term of a member shall be selected by a majority vote of all Board members at the last meeting prior to the expiration of the term of the member to be replaced.

(C) EFFECT OF VACANCY.—A vacancy on the Board shall not affect its powers, and shall be filled in the same manner in which the original designation or appointment was made.

(4) INCORPORATORS.—The initial members of the Board shall serve as incorporators and take whatever actions necessary to incorporate the Foundation.

(5) COMPENSATION.—Members of the Board appointed under subparagraph (C) of paragraph (1) shall receive reasonable allowances for necessary expenses of travel, lodging, and subsistence incurred in attending meetings and other activities of the Board, as set forth in the bylaws issued by the Board.

(c) EXECUTIVE DIRECTOR.—

(1) IN GENERAL.—The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of

the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) COMPENSATION.—The rate of compensation of the Executive Director shall be fixed by the Board.

(d) DUTIES.—The Foundation shall—

(1) provide funding for the support of the endowed scientists within the organizational structure of the intramural research programs of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration;

(2) recruit senior biomedical scientists to hold scientific positions as described in paragraph (1);

(3) support the staffing, equipment, and space requirements for the research undertaken by the scientists described in paragraph (2);

(4) support the stipends and research expenses of those individuals appointed under the National Institutes of Health Scholars program, who shall be appointed for 6-year terms;

(5) negotiate a memorandum of understanding with the Director of the National Institutes of Health and the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration that specifies that Foundation scientists and personnel shall observe the ethical and procedural standards regulating research and research findings, including publications and patents, that are followed by scientists and personnel at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration, including the Ethics in Government Act and the Technology Transfer Act; and

(6) conduct biennial audits of the financial condition of the Foundation.

(e) POWERS.—In order to carry out its duties under subsection (d), the Foundation is authorized to—

(1) operate under the direction of its Board;

(2) adopt, alter, and use a corporate seal, which shall be judicially noted;

(3) provide for one or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;

(4) hire, promote, compensate, and discharge officers and employees of the Foundation;

(5) prescribe by its Board its bylaws, that shall be consistent with law, and that shall provide for the manner in which—

(A) its officers, employees, and agents are selected;

(B) its property is acquired, held, and transferred;

(C) its general operations are to be conducted; and

(D) the privileges granted by law are exercised and enjoyed;

(6) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

(7) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subtitle;

(9) establish a mechanism for the selection of candidates, subject to the approval of the Director of the National Institutes of Health or the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, for the endowed scientific positions within the organizational structure of the intramural research programs of the National Institute of Health and the Alcohol, Drug Abuse, and Mental Health Administration and candidates for participation in the National Institutes of Health Scholars program;

(10) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(11) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(12) accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

(13) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;

(14) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation; and

(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subtitle.

(f) ADMINISTRATIVE CONTROL.—No participant in the program established under this part shall exercise any administrative control over any Federal employee.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such funds as the Secretary determines may be necessary to carry out this part, except that not more than $200,000 shall be appropriated to commence the initial operations of the Foundation, including the appointment of the Board under subsection (b). In the event that adequate amounts are not appropriated under this section, the Secretary shall make available not to exceed $200,000 from funds within the Department of Health and Human Services that are otherwise unobligated.

(h) REPEALER.—The provisions of this part shall be repealed on the date that occurs 5 years after the date of enactment of this part, except that this subsection shall not take effect if the Foundation has not yet been incorporated under subsection (a)(2) by such date.

PEER REVIEW

SEC. 507. [290aa–5] (a) * * *

* * * * * * *

(f)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in

paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding the inclusion of women and members of minority groups as subjects in the research.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 507A, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

SEC. 507A. INCLUSION OF WOMAN AND MINORITIES IN CLINICAL RESEARCH.

(a) GENERAL REQUIREMENTS.—In conducting or supporting clinical research for purposes of this title, the Secretary shall ensure that women and members of minority groups are included as subjects in each project of such research, subject to subsection (b).

(b) NONAPPLICABILITY.—

(1) IN GENERAL.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

(A) is inappropriate with respect to the health of the subjects;

(B) is inappropriate with respect to the purpose of the research; or

(C) is inappropriate under such other circumstances as the Secretary may designate.

(2) CRITERIA.—For purposes of paragraph (1), The Secretary shall by regulation establish criteria regarding the circumstances under which the inclusion of women and minorities in clinical research is inappropriate.

(c) ANALYSIS OF AFFECT ON WOMEN AND MINORITY GROUPS.—In the case of any project of clinical research in which women or members of minority groups are required under subsection (a) to be included as subjects in the research, the Secretary shall ensure that the project is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being tested in the research affect women or members of minority groups, as they may be, differently than other subjects in the research.

(d) NOTIFICATION.—Not later than January 1, 1991, the Secretary shall notify appropriate research entities and research grant recipients of the requirements concerning subsections (a), (b), and (c).

(e) CLINICAL RESEARCH EQUITY SUBCOMMITTEES.—

(1) ESTABLISHMENT.—The Secretary shall establish within the advisory council of each of the agencies of the Alcohol, Drug Abuse, and Mental Health Administration a subcommittee to be known as the Clinical Research Equity Subcommittee (hereafter in this subsection individually referred to as a "Subcommittee").

(2) DUTIES.—Each Subcommittee shall review all clinical research conducted by the agency for which the advisory council involved is established. The purpose of the review shall be determining the extent to which the research is being conducted in accordance with subsections (a) through (c). Such a review

shall be conducted not less than annually. Not later than 60 days after each such review, each Subcommittee shall submit to the Secretary and the Administrator a report describing the finding made as a result of the review.

(3) COMPOSITION.—Each Subcommittee shall be composed of not less than 6 members of the advisory council involved. The Secretary shall designate the membership of each Subcommittee from among members of the advisory council involved who have expertise regarding clinical research on diseases, disorders, or other health conditions—

(A) that are unique to women, more prevalent in women, or more serious for women; or

(B) for which the risk factors or interventions are different for women.

(4) APPOINTMENT OF ADDITIONAL MEMBERS.—If the Secretary determines that an advisory council for an agency of the Alcohol, Drug Abuse, and Mental Health Administration does not contain a sufficient number of individuals with the expertise required for purposes of paragraph (3), the Secretary shall appoint to the advisory council, from among individuals who are not officers or employees of the United States, a number of individuals necessary with respect to complying with such paragraph.)

(5) SUSPENSION OR REVOCATION OF RESEARCH AUTHORITY.—If the Secretary determines that any project of clinical research conducted by any agency of the Alcohol, Drug Abuse, and Mental Health Administration is not being conducted in accordance with subsections (a) through (c), the Secretary shall suspend or revoke the authority for the project under such conditions as the Secretary determines appropriate.

(f) DEFINITION.—For purposes of this section, the term "minority groups" means racial and ethnic minority groups.

* * * * * * *

HEALTH OMNIBUS PROGRAMS EXTENSION OF 1988

Public Law 100–607

* * * * * * *

SEC. 162. NATIONAL COMMISSION ON SLEEP DISORDERS RESEARCH.

(a) * * *

* * * * * * *

(h) DEVELOPMENT OF ESTIMATES.—The Commission shall recommend, for each of the Institutes of the National Institutes of Health *and the Alcohol, Drug Abuse and Mental Health Administration* whose activities are to be affected by the long-range plan, estimates of the expenditures needed to carry out each Institute's part of the overall program. Such estimates shall be prepared for the fiscal year beginning immediately after completion of the plan under subsection (g)(2) and for each of the next 2 fiscal years.

(i) REPORT.—Not later than [18 months] *24 months* after the initial meeting of the Commission (as prescribed by subsection (d)),

the Commission shall prepare and submit to the appropriate Committees of Congress, a final report describing—

* * * * * * *

○